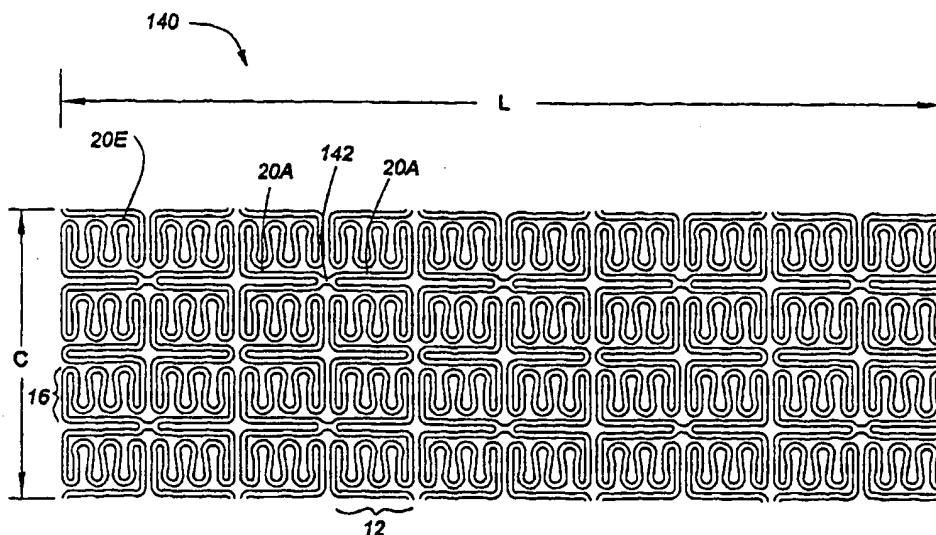




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(54) Title: EXPANDABLE INTRAVASCULAR TUBULAR STENTS



(57) Abstract

An expandable intravascular medical tubular stent (140) is a supporting device intended to maintain the walls of anatomical body channels or vessels, the stent being expandable within the vessel by an angioplasty balloon associated with a catheter thereby dilating and expanding the lumen of a vessel. The stent (140) comprises an arrangement of a plurality of radially expandable, serpentine members (16) arranged in interconnected rings. Upon inflation of the balloon, the stent expands in both radial and longitudinal directions in relation to the amount of radially-outwardly directed force by the balloon. The stent is designed such that during expansion, the longitudinal length of the stent is not substantially affected.

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EXPANDABLE INTRAVASCULAR TUBULAR STENTS

BACKGROUND OF THE INVENTION

5 Following an angioplasty procedure, the restenosis rate of stented vessels has proven significantly lower than for unstented or otherwise treated vessels, which treatments include drug therapy and other surgical procedures.

10 The intravascular stent functions as scaffolding for the lumen of a vessel. The scaffolding of the vessel walls by the stent serves to: (a) prevent elastic recoil of the dilated vessel wall; (b) eliminate residual stenosis of the vessel, a common occurrence in balloon angioplasty procedures; (c) maintain the diameter of the stented vessel segment slightly larger than the native unobstructed vessel segments adjacent the stented segment; and (d) as indicated by the latest clinical data, lower the restenosis rate.

15 The conventional stent designs suffer in varying degrees from a variety of drawbacks including: (a) the inability to negotiate bends in vessels due to columnar rigidity of the unexpanded stent; (b) the lack of structural strength, both radial and bending, of the unexpanded stent; (c) significant foreshortening of the stent during expansion; (d) limited stent length; (e) constant expanded stent diameter; (f) poor crimping characteristics; and (g) rough surface modulation of the unexpanded stent.

20 Although many stents are made of wire which is wound and bent into desired configurations, stents may also be formed using thin-walled tubes that are laser cut, or otherwise formed to allow the tubes to be compressed into a smaller diameter for delivery to a desired location within a body lumen. Such stents, commonly referred to as tubular stents, provide advantages in terms of increased torsional stability and hoop strength as compared to stents formed from
25 wires. One disadvantage, however, is that tubular stents typically exhibit limited longitudinal flexibility which can limit delivery through tortuous pathways and their deployment in curved body lumens.

As a result, a need exists for a stent that provides the longitudinal flexibility associated with wire-wound stents in combination with the hoop strength and torsional stability of a tubular stent.

5 A review article, *Does Stent Design Influence Restenosis?*, by Dr. J. Gunn published in the *European Heart Journal* July 1999 (Vol. 20, issue14), stated that unlike restenosis after balloon angioplasty, the in-stent restenosis consists predominantly of neointimal growth rather than the combination of neointima, recoil and downsize remodelling seen after the balloon angioplasty. The degree of restenosis is related to the extent of damage done at the time of implantation. The composition of the neointima of in-stent restenosis is similar to that seen
10 in balloon angioplasty, and includes vascular smooth muscle cells and inter-cellular matrix. Any subtle differences in the composition of the neointima of the in-stent restenosis and post-balloon injury, for example a suggestion of more matrix relatives to cell in the former, may be explained by the different nature and time-course of the two injuries: stent struts produce local deep trauma, and the stent as a whole produces chronic stretch; whereas balloon injury,
15 which may also be deep, is transient and tends to be focal, with unilateral dissection rather than circumferential stretch. There is clinical evidence that the stent geometry influences in-stent restenosis. One widespread perception is that tissue prolapse at the central articulation of the Palmaz-Schatz stent (U.S. Patent No. 5,382,261 to Palmaz dated January 17, 1995) increases in-stent restenosis at that site. Intravascular ultrasound has also revealed that in-stent
20 restenosis within coil-stents is related to recoil, whereas in-stent restenosis within slotted tube stents is related to sub-expansion. In a retrospective study of matched lesion, the flexible Micro Stent™ from Arterial Vascular Engineering, Inc. of Santa Rosa, California., was associated with a higher restenosis rate than the more rigid Palmaz-Schatz stent. Similarly, a coil-stent has been shown to be associated with increased in-stent restenosis compared with
25 a slotted tube stent in chronic total occlusions, a situation where radial strength is probably paramount.

In one systematic study, where the features of stent geometry which make one stent superior to another were investigated, changing the stent configuration to reduce strut-strut intersections reduced the vascular injury score by 42%, thrombosis by 69% and neointimal hyperplasia by
30 38%. Coating with an inert polymer did not alter vascular injury or neointimal hyperplasia, although thrombosis was eliminated. Uniform (modest oversize) deployment of multiple examples of one design of stent in normal porcine coronary artery, with many sections analysed at a consistent time point, allows precise mathematical analysis of the relationship

between as many parameters of the stent geometry as are thought useful in in-stent restenosis. Using this technique, extreme strut protrusion, large inter-strut distance, fracture of the internal elastic lamina, medial compression and location near the distal ends of the stent have been identified as of particular importance. There was no direct relationship found between the number of struts and in-stent restenosis unless the stent was over-deployed, in which case more struts were advantageous, presumably distributing the forces of stretch more evenly and preventing isolated strut protrusion. In the same study, there was great lumen loss and neointimal growth at the distal end compared with the middle of the stents, possibly reflecting the taper seen in a porcine artery. There was suggestion that eccentricity of the stent deployment (oblateness of the cross-section) adversely affected in-stent restenosis. There is clinical intravascular ultrasound-based evidence for this, too. In one study, deviation from the circular in a stented vessel is associated with a trend towards increased target vessel revascularization at long-term follow-up. In contrast to the early days of stenting, when the fear of a "foreign body" reaction was still present, results such as this now point away from a minimalist approach towards generous coverage of the wounded vessel wall, with a high metal/artery ratio. The concept of maximizing the metal barrier is, of course, limited by poor "crimpability", unacceptable profile and inflexibility. Such designs (for example, the Jomed covered stent made by Jomed Implantate GmbH of Rangendingen, DE) are already marketed, but have not yet reached wide acceptance.

Deployment strategies are also likely to affect the long-term result of stenting. Finite element analysis has revealed that low balloon compliance and the lowest possible balloon pressure to achieve adequate deployment are important variables. Balloon -(and stent)- artery ratio (BAR) are also contributory. In his early studies, Schwartz (*J Am Coll Cardiol* 1992;19:267-274) used a BAR of 1.5:1, and produced dramatic injury with a high experimental animal mortality rate. Thomas (*J Invas Cardiol* 1997;9:453-460), however, using a BAR of 1.1:1, experienced 100% patency and minimal neointima. In trying to draw any conclusion from the data available about the "ideal" stent, a pattern is starting to emerge. Whilst preserving the desirable characteristics of low profile, trackability, conformability and visibility, a stent should have many, closely spaced struts giving good, well-distributed radial strength. The inter-strut connections, whilst allowing for even balloon expansion and access to side-branches, should form a close meshwork which prevents large spaces from opening up between the struts, or from one strut protruding radially beyond its neighbours. The forces for expansion should be distributed evenly so that the stent expands symmetrically, without

eccentricity. Attention should be paid to the design of the ends of the stent, so that a smooth transition to normal vessel is created, and distal oversizing is avoided. The design should preclude the development of large defects in metal coverage. Sizing of the stent relative to the normal "reference" segment should not be over-zealous, especially where a long stent is used.

5 The diameters of some preferred stents, when in the compressed state for delivery to a desired location within a body lumen is typically from about two to about three times less than the diameter of the stents when in their expanded state. For example, typical stents may have a compressed external diameter of about 1 millimeter to about 3 millimeters for delivery and an expanded external diameter in a body lumen of about 3 millimeters to about 15 millimeters
10 when released from compression in a large arterial vessel.

The metal surface coverage as a function of stent diameter is calculated by dividing the total vessel contact metal surface area of the stent structure by the surface area of the vessel at any given stent/vessel diameter. There is inverse relationship between the metal surface coverage and the stent expansion (the more expansion of the stent, the less metal surface coverage).

15 The two most important features of the coronary stent are basic to its use: flexibility is required only during insertion and until deployment of the stent at the target lesion. Rigidity is required to supply long term support to the vessel wall, but only from the moment of deployment and on.

20 In a description of the Iris stent (which is a slotted tube stent made of 316L stainless steel by Uni-Cath Inc. of Saddle Brook, New Jersey, U.S.A.) by Albert Tashji published in the *Handbook of Coronary Stents*, second edition, 1998, chapter 24 (see also U.S. Patent Number 5,911,754, issued June 15, 1999), the expansion data observed is shown in Table 1.

STENT DIAMETER		LENGTH	SHORTENING	METAL COVERAGE
(mm)	(inches)	(mm)	(%)	(%)
1	0.04	16.9	--	55.4
2.5	0.098	16.1	4.7	21.9
3	0.118	16	5.3	18.6
3.5	0.138	15.1	10.7	17
4	0.157	14	17.2	16.2

30 Table 1

The NIR stent by SCIMED MEDTRONICS (SciMed Life Systems, Inc. of Maple Grove, MN, U.S.A. and Medtronic, Inc. of Minneapolis, MN, U.S.A.) is a multi-cellular slotted tube design made of 316L stainless steel. The multi-cellular design comes in two types to cover different vessel diameters. The 7-cell circumflex unexpanded stent will expand by different size balloons to cover vessel diameters that range from 2.5mm to 3.5mm. The metal to artery percentage ratio for the 7-cell will range from 24% at 2.5mm to 14% at 3.5mm expansion and the stent foreshortening ranges from 7% at 3.5mm to 14% at 4.0mm expansion. In order to prevent further reduction of the metal to artery percentage ratio and foreshortening of the stent at expansion higher than 3.5mm, a second stent is provided where the external diameter of the circumflex unexpanded stent is increased to 9-cell in order to expand up to 5mm. The metal to artery percentage ratio for the 9-cell will range from 14% at 3.0mm to 11% at 5.0mm expansion and the stent foreshortening ranges from 7% at 3.5mm to 14% at 5.0mm expansion (PMA application # P980001, published by the FDA in August 11, 1998). The drawback of the increase of the external diameter of the unexpanded stent will effect the flexibility, because there is inverse relationship between the external diameter and the flexibility of the unexpanded stent.

SUMMARY OF THE INVENTION

Accordingly, one object of the invention is to provide a flexible stent which can be easily delivered through meandering and narrow arteries or other body lumens.

Another object of the invention is to provide the stent as stated above, which can substantially prevent shortening of the entire length of the stent when it is expanded. It is further objection of the present invention to provide a stent which does not substantially change in length or at least does not reduce in length as the stent diameter expands during balloon expansion.

A further object of the present invention is to provide a stent with a low profile when crimped over a delivery balloon of the stent assembly.

A further object of the present invention is to provide a stent with generous coverage of the wounded vessel wall, with a high metal/artery ratio. It is further objection of the present invention to provide a stent with a closely spaced struts giving good, well-distributed radial strength.

Another object of the invention is to provide the stent with a compressed state or unexpanded diameter for delivery to a desired location within a body lumen which allow a gradual increase up to five times the initial diameter of the stent upon expansion. It is a further object of the present invention to provide a controlled expansion of the stent to avoid oversizing of the stent relative to the normal "reference" segment.

Accordingly there is provided in one aspect of this invention an intravascular tubular stent expandable between a first, constricted state and a second state of greater expanded diameter; the stent comprising in its constricted state;

a plurality of radially expandable rings each formed of a plurality of circumferentially extendable elements, each circumferentially extendable element comprising at least one functional unit having a bendable joint from which a pair of arms extend, said arms converging toward their ends distal the bendable joint so as to form an elongate converging opening therebetween; and

each pair of adjacent radially expandable rings being connected to each other at at least one location.

In another aspect of the invention, there is provided an intravascular tubular stent expandable between a first, constricted state and a second state of greater expanded diameter; said stent comprising in its constricted state:

a plurality of radially expandable rings each formed of a plurality of circumferentially extendable elements, each circumferentially extendable element comprising one or more U-shaped elements having a bendable joint from which a pair of arms extend generally parallelly, said arms defining therebetween a generally constant width opening which opens away from said bendable joint, said constant width opening being arranged in a diagonal orientation with respect to the longitudinal axis of the stent; and

each pair of adjacent radially expandable rings being connected to each other at at least one location.

In still a further aspect of the invention, there is provided a self-compensating, radially expandable tubular stent comprising:

a plurality of interconnected radially expandable rings each formed of a plurality of circumferentially extendable elements each consisting of one or more over-parallel U-shaped elements having an elongate converging opening defined between converging arms thereof.

In general, the design geometry of the subject stents is such that substantially no shortening of the stent occurs throughout expansion and over the viable working range of the stent. These and other objects and advantages of the present invention are described in the following description and illustrated by way of drawings.

5 BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a schematic drawing illustrating a tubular stent in its unexpanded, pre-deployment state; and Fig. 1B is a schematic drawing similar to that of Fig. A, but showing the stent in a radially expanded state;

10 Figs. 2A to 2C are schematic drawings showing a flattened portion of the cylindrical contour of the various tubular stents;

Figs. 3A through 3I are schematic drawings showing various stent elements for describing their mechanics during expansion;

15 Fig. 4A is a schematic showing a flattened portion of the cylindrical contour of a prior art stent, while Fig. 4B is a schematic of a flattened portion of a stent in accordance with the present invention; and Fig. 4C is an illustration of the stent portion show in Fig. 4B but in its expanded state.

Figs. 5 to 15 are schematic drawings showing alternate embodiments of the stent according to the present invention as a flattened portion thereof;

20 Fig. 16A is a magnified plan view of a dissected and laid flat stent prototype made in accordance with the present invention; Fig. 16B is a greatly enlarged detail section of Fig. 16A; and Fig. 16C is a schematic showing a flattened portion of the stent of Fig. 16A but shown in its expanded state; and

Figs. 17 to 19 are schematic drawings showing further stent embodiments made in accordance with the teachings of the invention.

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DETAILED DESCRIPTION OF THE INVENTION

FIG. 1A illustrates schematically a simple form of a stent 10 shown in its constricted state, i.e. prior to the deployment and expansion. In general, the stent 10 comprises a plurality of interconnected radially expandable rings 12 arranged coaxially so as to form a generally
30 tubular structure having a longitudinal axis 14. Each pair of adjacent rings 12 is

interconnected by at least one interconnection member 15. The stent of the present invention is operable with two or more such rings 12, the number of which is generally dependent on specific structure of the rings and how they are interconnected as well as the desired length of the stent. Each ring 12 comprises a series of expandable elements 16 connected together in a circular contour. As shown schematically in Fig. 1B, in response to the radially outwardly directed expansion force of a pressurized balloon inserted through the ring 12, each expansion element 16 expands along the generally increasing circumferential contour of the stent 10'.

Figs. 2A, 2B and 2C show, for explanatory purposes, specific examples of portions of stents 10A, 10B and 10C, laid flat for illustrative purposes. Stents 10A, 10B and 10C comprise a plurality of coaxially-arranged annular rings 12. Each ring 12 consists of a series of connected elements 16 which are circumferentially expandable. Adjacent pairs of rings 12 are interconnected by interconnecting elements 15 which can be generally linear as shown or can themselves be expandable or contractible longitudinally with respect to the axis of the stent in response to the expansion of the rings 12. In this regard, attention is directed to Applicant's copending International Application No. PCT/CA99/00632 filed July 12, 1999 and entitled "Expandable Endovascular Medical Tubular Stent", the entirety of which is incorporated herein by reference, which contains illustrations of a variety of different arrangements for the elements that constitute the stent.

In general, the aforementioned stents 10A, 10B and 10C and, in particular, the extendable elements 16, can be considered to comprise one or more "functional units" each of which, roughly speaking, is an element that doubles-back on itself so as to form a pair of "arms" which are attached at one end and separated at their other thus resulting in a "U", "V" or "C" shape, for example. In the exemplary stents 10A, 10B and 10C shown in Figs. 2A, 2B and 2C, these functional units are U-shaped and are oriented such that their "arms" or their "openings" are disposed either parallel with or transverse to the stent axis 14. Figs. 3A and 3C illustrate such functional units 20A and 20B, respectively. Fig. 3A shows a functional unit 20A of length L_1 having a pair of generally parallel arms 22,24 connected by a deformable or bendable joint 26. The arms 22,24 are spaced apart a circumferential distance C_1 by an opening 28. Opening 28 as well as arms 22,24 are disposed generally parallel with the longitudinal axis 14 of the stent. In general, many prior art stents utilize such parallelly-oriented functional units or variations thereof in their construction, including Applicant's prior U.S. Patent No. 5,755,776, issued May 26, 1998 and entitled "Permanent Expandable Intraluminal Tubular Stent", which is also incorporated herein by reference.

Fig. 3B demonstrates the changes to the functional unit 20A' during radial expansion of the stent. In general, initial deformation takes place in the bendable joint 26 and both the arm members 22,24 move diagonally away from each other in the opposite (i.e. circumferential) direction which results in an increase of the circumferential distance C_1' which results in an overall increase in the circumference of the stent 10 during expansion. At the same time, the length L of the functional unit 20A will be reduced to a length L_1' which, in turn, results in overall foreshortening of the stent 10.

In order to avoid the foreshortening of the functional unit 20A,20A', a change in the orientation is needed as shown in the functional unit 20B in Fig. 3C in which the arm members 22,24 are disposed generally perpendicular to the longitudinal axis 14 of the stent 10 and connected by bendable joint 26 arranged generally parallel to the longitudinal axis 14. In this case, the axial length of the functional unit 20B is shown as L_2 while its circumferential length is shown as C_2 . If the arm members 22,24 are caused to move diagonally away from each other, this will result (see Fig. 3D) in an increase of the length L_2 of the functional unit 20B to L_2' which, in turn, will result in overall increase in the length of the stent 10. At the same time, there will be a decrease in the circumferential length C_2 of the functional unit 20B to C_2' which will result in a reduction of the circumference of the stent 10 and this reduction is at odds with the desired capability for expansion.

To reach an optimum state between Figs. 3A and 3C, there is provided in Fig. 3E a diagonally-oriented functional unit 20C in which the arm members 22,24 have a diagonal orientation with respect to the longitudinal axis 14 of the stent 10. The arms 22,24 are connected by a bendable joint 26 also arranged diagonal to the longitudinal axis 14 of the stent 10. The functional unit 20C has a length L_3 and the ends of the arms 22,24 are separated a circumferential distance C_3 . Upon radial expansion (as shown in Fig. 3F), arm members 22,24 of the functional unit 20C' move diagonally away from each other in the opposite direction which results in increase of the circumferential distance C_3' which, in turn, results in overall increase in the circumference of the stent 10 during expansion. At the same time, the length L_3' of the functional unit 20C' will be at least be maintained with respect to initial length L_3 or non-significantly reduced which will result in practically no foreshortening of the stent 10 during expansion.

Another alternative to prevent foreshortening of the functional unit is shown in Fig. 3G in which the functional unit 20D having a length L_4 has its two arm members 22,24 angled towards one another each at an angle α from parallelity with the stent axis 14 so that the

opening 28 is narrower at the ends of the arms 22,24 distal the bendable joint 26 than at their proximal ends. This arrangement is termed herein as "over-parallel". The advantage to this over-parallel arrangement is that where the ends distal the bendable joint are spaced an initial circumferential distance C_4 , circumferential expansion initially opens the arms 22,24 through to parallelity as shown in Fig. 3H whereat the ends of the distal arms 22,24 are spaced apart a greater distance C_4' while the length of the functional unit 20D' expands slightly to L_4' . Continued radial expansion causes further widening of the circumferential distance to C_4'' (termed "under-parallel") as shown in Fig. 3I, resulting in an overall increase in the circumference of the stent 10. However, as the arms 22,24 diverge from parallel, the overall length L_4'' of the functional unit 20D'' will start to reduce from L_4' . When the angle $\alpha'' = \alpha$, length L_4'' will equal the initial length L_4 and while there has been a circumferential expansion to C_4'' , no overall shortening of the functional unit 20D has resulted. Of course, further radial expansion will start to foreshorten the functional unit 20D'' as compared with its original length. Of importance, however, is that in comparing the functional units 20A and 20D of Figs. 3A and 3G, respectively, for a given amount of circumferential expansion, the axial shortening of the former will necessarily be greater than that of the latter. Alternately stated, for a given reduction in length of one of these functional units, a greater circumferential expansion can be achieved by the functional unit 20D of Fig. 3G than the functional unit 20A of Fig. 3A. Accordingly, these advantageous principles can be incorporated into the design of stents to achieve the desired minimization or elimination of axial reduction upon radial/circumferential expansion.

Figs. 4B and 4C illustrate the principle of the over-parallel functional unit 20D of Fig. 3G as applied to the substantially rectilinear stent design 40 as shown in Fig. 4A, which is derived from Applicant's aforementioned U.S. Patent No. 5,755,776. Stent 40 comprises a plurality of circular rings 12 arranged coaxially with respect to stent axis 14. Each ring 12 comprises a plurality of circumferentially expandable elements 16 arranged in a generally serpentine or square wave-form pattern about the cylindrical contour of the stent. The arrangement of circumferentially expandable elements 16 in one ring 12 is such that the adjacent ring 12 is the mirror opposite in the axial direction. Thus, the openings 28 of the expandable elements 16 of one ring 12 oppose the openings 28 of the expandable elements 16 of an adjacent ring 12, whereas the "joints" 26 of the expandable elements 16 are disposed immediately adjacent the joints 26 of the adjacent ring 12. By interconnecting adjacent pairs of rings 12 by at least one interconnecting member 15 per pair from the "bottom" 42 of an expandable element 16 to the

bottom 42 of an adjacent expandable element 16, the stent 40 resists reduction in length upon radial expansion as explained in Applicant's aforementioned U.S. Patent No. 5,755,776. In the stent 50 shown in Fig. 4B, the joints 26 between the pairs of arms 22,24 are rounded and the arms 22,24, which are generally linear, are angled toward one another so as to form an expandable element 16 with a convergent opening 28 which is the same as the over-parallel functional unit 20D of Fig. 3G. The expandable element 16 alternately repeats itself so as to form a serpentine or sinusoidal ring 12. Stated alternately, the arm 22 for one expandable element 16 is shared as one arm 22 of the circumferentially adjacent expandable element 16 as shown in Fig. 4B. Interconnecting members 15 connects the bottom 42 of one expandable element 16 to an opposed expandable element 16 so as to function in the same manner as the interconnecting member 15 of the stent 40 of Fig. 4A as aforesaid. Upon radial expansion of the stent 50 as shown in Fig. 4C, the diverging of the arms 22,24 initially causes each ring to lengthen in the axial direction of the stent 50 and, only once the arms 22,24 are past parallel, do the rings 12 start to shorten. Thus, the propensity for shortening upon radial expansion of the stent 50 of Fig. 4B is even further reduced as compared with the arrangement of Fig. 4A in accordance with the previously discussion with respect to functional unit 20D of Fig. 3G.

Variations of the stent 50 of Fig. 4B are shown in Figs. 5 and 6 as stents 60,70 in their compressed (i.e. unexpanded), pre-deployment state. In Fig. 5, the ring interconnecting member 62 essentially takes the place of an adjacent pair of expandable elements 16' as shown in stippled lines. As with the arrangement shown in Fig. 4, interconnecting member 62 serves to reduce the longitudinal reduction of the stent 60. The presence of the over-parallel functional units 20D serve to further reduce the amount of foreshortening. In order to increase axial flexibility, the stent 70 of Fig. 6 is provided with a relatively short interconnection member 64s between adjacent rings 12. Enhanced axial flexibility is important in the undeployed stent to enable the stent to be delivered to a desired location via a tortuous vessel.

The stents 50,60,70 shown in Figs. 4B,5, and 6 comprise a plurality of the over-parallel functional units 20D disposed generally parallel with respect to the longitudinal axis 14 of the respective stent (i.e. the openings 28 are aligned generally parallel as shown in Fig. 3G). However, Applicant has found as explained in his aforementioned International Application No. PCT/CA99/00632, that by orienting at least some of the roughly linear components of the circumferentially expandable elements 16 in the circumferential direction, such as is shown in Figs. 2A-2C, self-compensation of the longitudinal shortening of the stent occurs due to the longitudinal expansion of each ring 12 coupled with the reduction in distance between adjacent

rings. By orienting at least some over-parallel functional units in the circumferential direction, even further radial expansion is possible while still maintaining the self-compensating feature of the stent, thus resulting in a greater expansion range with little or no change in the length of the stent over the working range.

5 In this regard, there is provided in Fig. 7 one embodiment of the invention which includes a plurality of rings 12 each comprised of a series of circumferentially expandable serpentine elements 16. Each expandable element 16 is comprised of a plurality of over-parallel functional units 20E oriented generally circumferentially or perpendicular to the longitudinal axis 14 of the stent 80. Adjacent rings 12 are interconnected at selective locations 82 whereat
10 the bendable joint 26 of one over-parallel functional unit 20E is integrally formed, fused or otherwise attached to the bendable joint 26 of an adjacent over-parallel functional unit 20E. In other words, the external apexes of adjacent bendable joints 26 are attached. With this stent 80, each expandable element 16 is connected to the next in the series by way of a further over-parallel functional unit 20F oriented generally parallel to the axis 14.

15 Fig. 8 shows a stent 90 which is a variation of the stent 80 embodiment of Fig. 7 having substantially identical rings 12 comprised of a series of expandable elements 16, each being a horizontal mirror image to the next in the series. The rings 12 themselves are vertical mirror images of the adjacent ring 12. However, the rings 12 in this embodiment are interconnected in the same manner as the stent 50 of Fig. 4B, that being an interconnecting member 15 which
20 extends from the bottom of one axially aligned, over-parallel functional units 20F to the bottom of an opposed over-parallel functional unit 20F.

The stent 100 shown in Fig. 9 is similar to the stent 80 of Fig. 7 except that the arms 22A, 24A of the circumferentially aligned over-parallel functional units 20E which are on the outermost sides of each expandable element 16 are circumferentially aligned. Between circumferentially
25 adjacent expandable elements 16, an axially-aligned functional unit 20A, such as shown in Fig. 3A is provided.

The stent 110 shown in Fig. 10 comprises a plurality of rings 12, each identical to its adjacent ring 12. While as with the Fig. 7 and Fig. 8 embodiments, adjacent bendable joints 26 are interconnected by member 15, due to the geometry, the bottom of one axially-aligned over-parallel functional unit 20F is attached by member 15 to the apex of an adjacent axially-aligned over-parallel functional unit 20F'.
30

The interconnection of the adjacent rings 12 can take on various forms as already shown in Figs. 7 to 10 and as shown in Figs. 11 to 15. In Fig. 11, selective adjacent portions 120 of circumferentially expandable elements 16 of adjacent rings 12 may be integrally formed, fused or otherwise attached to form the connection. In Fig. 12, an interconnecting element 122
5 extends between a portion of one expandable element 16 of one ring 12 and a portion of another expandable element 16' in an adjacent ring 12'. In this case, the expandable element 16 is not axially adjacent the expandable element 16'. The interconnecting member need not be linear and may take a variety of different shapes to promote better axial flexibility of the stent, maintaining the axial length of the stent, and/or to provide additional vessel wall support and, hence, greater metal coverage. As shown in Fig. 12, the interconnecting member 122 is
10 serpentine or N-shaped which is geared toward promoting separation between rings 12,12' during expansion. In Fig. 13, the interconnecting member 124 is shown as triple-S-shaped which tends to increase the metal content, increase the radial strength and serves to fill the larger gaps for more complete support. In Fig. 14, the interconnecting member 126 is disposed
15 between portions of adjacent expandable elements 16 of adjacent rings. In this case, interconnecting member 126 is shown as U-shaped but any one of a variety of shapes may be employed. Fig. 15 illustrates more complex interconnecting mechanisms 128,130. Interconnecting mechanism 128 comprises a first interconnecting member 128A disposed
20 between portions of adjacent expandable elements 16 of adjacent rings 12,12' and a second interconnecting member 128B disposed between portions of adjacent expandable elements 16 of adjacent rings 12,12'. The interconnecting members 128A,128B are integrally formed, fused or otherwise attached to each other. The cloverleaf design of the interconnecting members 128A,128B permits some local axial and circumferential expansion. Interconnecting mechanism 130 comprises a first interconnecting member 130A disposed
25 between non-adjacent portions expandable elements 16 of adjacent rings 12',12 and a second interconnecting member 130B disposed between non-adjacent portions of adjacent expandable elements 16 of adjacent rings 12',12. Both the interconnecting members 130A,130B are N-shaped with their central leg portions crossingly attached. The interconnecting mechanisms 128,130 serve to increase the metal coverage, which will give more radial support and reduce
30 the gaps between the struts/members, and can be designed to limit the radial expansion of the stent so as to reduce the risk of stent rupture by overinflation.

Fig. 16A shows a complete portion of a stent 140 (as laid flat) in accordance with a prototype of the present invention which is similar to the stent portion 100 of Fig. 9 except that the

expandable element 16 includes an additional circumferentially-oriented, over-parallel functional unit 20E. In addition, adjacent rings 12 are interconnected by a relatively short interconnecting member 142 to facilitate axial flexing. As can be seen, the stent 140 provides substantial metal coverage when in its unexpanded state shown in Fig. 16A. The length L = 15.851mm and the distance C, which is the circumference is 4.393mm which results in a tubular stent of approximately 1.37mm diameter. Fig. 16B illustrates an enlarged section of the stent 140 of Fig. 16A. For reference purposes, Table 2 sets out the length L and radius R dimensions (in mm) as measured:

L ₁	L ₂	L ₃	L ₄	L ₅	L ₆	L ₇	R ₁	R ₂	R ₃	R ₄	R ₅	R ₆	R ₇	R ₈
0.846	0.563	0.398	0.07	0.08	0.08	0.08	0.14	0.14	0.09	0.165	0.05	0.06	0.131	0.05

Table 2

The thickness of the material, i.e the stent's tubular wall thickness is on the order of about 0.05-0.2mm.

Fig. 16C shows a portion of the stent 140 in its expanded form as 140'. The expandable elements 16' have started to move diagonally and the axially-oriented functional units 20A' have expanded circumferentially to an "under-parallel" disposition. The rings 12' are prevented from separation by interconnecting members 142'. The expansion causes a tensile force component to be exerted along the expandable element 16', causing the individual functional units 20E' expand from their originally over-parallel disposition to parallel as shown in Fig. 16C and with sufficient expansion, to an under-parallel disposition.

Table 3 sets out the results of radial expansion testing the stent 140.

STENT DIAMETER		LENGTH	SHORTENING	METAL COVERAGE
(mm)	(inches)	(mm)	(%)	(%)
1.37	0.054	16	--	52
3	0.118	16	0	24
3.5	0.138	16	0	20
4	0.157	16	0	17

Table 3

As can be seen from Table 3, the length of the stent 140 remains the same over the range from its nominal, unexpanded diameter of 1.37mm to 4mm. These results can be compared with the results of Uni-Cath, Inc.'s Iris stent as shown in Table 1, which show stent length reduction as expansion increases. In addition, the stent 140 retains acceptable metal coverage over the expansion range.

The self-compensating principle as described above with respect to the diagonally-oriented functional element 20C of Fig. 3E, can also be combined with the aforementioned over-parallel concept for axially- or circumferentially-oriented functional elements 20D, 20E and arranged to optimize axially flexibility for ease of deployment without significant detriment to strength of the expanded stent after deployment. To illustrate the combination of these principles, there is shown in Fig. 17 a stent 150 comprising a plurality of similar rings 152. Each ring 152 consists of an alternating series of over-parallel functional elements 20G which are arranged diagonally with respect to the longitudinal axis 14 of the stent 150. Each ring 152 forms a separate oblique cylinder and is not part of a "helical winding", and accordingly, the end rings 152 are not as prone to splaying as would be the case with a free end portion of a helical winding.

As with the stent 50 of Fig. 4B, adjacent rings 152 are interconnected with an interconnecting member 154 between opposed bendable joints 156. The interconnecting members can be attached in an number of ways, such as for example, bottom-to-bottom as shown, apex-to-apex as shown in Fig. 16A, or apex-to-bottom as shown in Fig. 10. Similarly, to increase the flexibility as aforesaid, the length of the connecting member 164 between adjacent rings 162 can be reduced as aforesaid and as illustrated in Fig. 18.

The diagonally-oriented functional unit 20C concept can also be employed in a stent without use of the over-parallel feature of Fig. 3G to substantially the same advantage. By way of example, stent 170 of Fig. 19 is constructed of a plurality of obliquely disposed rings 172. Each ring 172 consists of a series of circumferentially expandable elements 16 in this case connected to the next expandable element in the series by a diagonally-disposed functional unit 20C. Each expandable element comprises one or more diagonally-oriented functional units 20C' which in this case are disposed generally at right angles to the diagonally-disposed functional unit 20C. Selected apexes of adjacent bendable joints 176 of adjacent rings 172 may be attached at 174 to form the ring interconnections or the interconnecting can be

accomplished in any of the manners discussed in this application or in Applicant's aforementioned International Application No. PCT/CA99/00632.

5 The stents described herein are preferably fabricated from biocompatible, low memory, more plastic than elastic material to permit the stent to be expanded and deformed, yet sufficiently rigid to permit the stent to retain its expanded and deformed configuration with an enlarged diameter and also to resist radial collapse.

10 Typically, stents in accordance with the teachings herein may be expanded up to about four times their original constricted diameters yet still have desirable properties of good axial flexibility in the constricted state and resistance to radial collapse and comprehensive wall support in the expanded state. Accordingly, stents may be provided for example in nominal diameters d of about 1mm, 1.5mm, and 2mm which, depending on the specific structure, may be expanded to 4mm, 6mm or 8mm, respectively, which should enable a minimum number of stents to be employed in most situations. It should be borne in mind that the stents of the present invention are operable over their entire range because they deform substantially continuously under application of an radially outwardly directed force. Upon removal of the force, deformation halts and the stent remains sufficiently rigid to withstand the radial force of the wall which it supports.

20 Suitable materials for the fabrication of the tubular stent would include silver, tantalum, stainless steel (316 L), gold, titanium, NiTi alloy or any suitable plastic materials such as thermoplastic polymers. Any medically-suitable metal which is capable of yielding plastically under the typical forces of a balloon catheter could also be employed. Alternatively, the stent may be made of a radioactive material or irradiated with a radioactive isotope. The radioactive isotope may be a beta particle emitting radioisotope. By using a stent made of the radioactive material, cancer cells in and around the stent can be deactivated or killed. Alternatively, the stent can be coated with materials that prevent cell overgrowth. The stent may be coated with an anticoagulating medication substance, such as heparin, and/or a bioabsorbable material. Accordingly, when the stent is used in a blood vessel, blood clotting can be prevented. Also, the stent may have pores, indentations or a roughened surface capable of absorbing or retaining a drug therein/thereon for slowly releasing the same over time. Thus, when the stent with a drug is implanted in the body lumen, the drug can slowly released in the body lumen. To enhance visibility of the stent when viewed by various different medical imaging devices, the end rings can be formed from a radio-opaque material, such as gold, silver or platinum, which

allows both ends of the stent to be clearly visible through a medical imaging device during or after implantation of the stent within a body lumen of the patient.

5 The stent is preferably formed by laser cutting technology wherein the pattern is cut into a cylindrical section of the appropriate material. Other suitable methods may be used, for example, the stent can be formed by an etching technique. Namely, a pattern of the rings and the interconnecting members are coated on a cylindrical metal member, which is etched in an acid solution. Then, un-coated portions are removed.

10 The thickness of the material, i.e the stent's tubular wall thickness is on the order of about 0.05-0.2mm. The cross-sectional configuration of the material can be varied, although it will likely depend upon the manner in which the stent is manufactured. For, example, using laser cutting on a piece of tubular material, the resulting members which are disposed in the circumferential direction will have roughly rectangular cross-sections while the members generally parallel to the longitudinal axis will likely have a slightly trapezoidal cross-section if the axis of the laser intersects the axis of the tubular material. A more rectangular cross-section would be obtainable with an appropriate offset of the laser's axis.

15 Having described this invention with regard to specific embodiments, it is to be understood that the invention has been described with respect to a limited number of embodiments. It will be appreciated that many variations, modifications and other applications of the invention may be made. Accordingly, the invention is therefore to be limited only by the scope of the
20 appended claims.

I CLAIM:

1. An intravascular tubular stent expandable between a first, constricted state and a second state of greater expanded diameter; said stent comprising in its constricted state:

5 a plurality of radially expandable rings each formed of a plurality of circumferentially extendable elements, each circumferentially extendable element comprising at least one functional unit having a bendable joint from which a pair of arms extend, said arms converging toward their ends distal the bendable joint so as to form an elongate converging opening therebetween; and

10 each pair of adjacent radially expandable rings being connected to each other at at least one location.

2. The intravascular tubular stent as claimed in claim 1, wherein said functional unit is oriented such that the elongate opening is disposed generally parallel to the longitudinal axis of the tubular stent.

15 3. The intravascular tubular stent as claimed in claim 1, wherein said extendable element comprises a plurality of functional units arranged such that the elongate openings are disposed generally circumferentially perpendicular to the longitudinal axis of the tubular stent.

4. The intravascular tubular stent as claimed in claim 1, wherein each expandable ring is substantially identical to each adjacent ring.

20 5. The intravascular tubular stent as claimed in claim 1, wherein each expandable ring is the mirror-image in the axial direction to each adjacent ring.

6. The intravascular tubular stent as claimed in claim 1, wherein each expandable ring is disposed obliquely with respect to the longitudinal axis of the stent.

25 7. The intravascular tubular stent as claimed in claim 6, wherein said functional unit is oriented such that the elongate opening is disposed diagonally with respect to the longitudinal axis of the stent.

8. The intravascular tubular stent as claimed in claim 1, wherein circumferentially adjacent extendable elements are connected by radially expansible connection means.

9. The intravascular tubular stent as claimed in claim 8, wherein the radially expandible connection means comprises a U-shaped connector having a pair of arms between which a constant opening is defined, said constant opening of said U-shaped connector being disposed substantially parallel to the longitudinal axis of said stent.

5 10. The intravascular tubular stent as claimed in claim 8, wherein said radially expandible connection means comprises a further functional unit whereby the elongate opening thereof is disposed substantially parallel to the longitudinal axis of said stent.

10 11. The intravascular tubular stent as claimed in claim 1, wherein at least one interconnecting member extends between a portion of one ring and an adjacent portion of an adjacent ring.

12. The intravascular tubular stent as claimed in claim 11, wherein the at least one interconnecting member extends between a bendable joint of one extendable element to the bendable joint of another extendable element in an adjacent ring.

15 13. The intravascular tubular stent as claimed in claim 12, wherein said one extendable element is longitudinally adjacent the another extendable element in the adjacent ring.

20 14. The intravascular tubular stent as claimed in claim 11, wherein said at least one interconnecting member extends between one of a plurality of connecting members disposed between circumferentially adjacent extendable elements of one ring to one of another plurality of connecting members disposed between circumferentially adjacent extendable elements of an adjacent ring.

15. The intravascular tubular stent as claimed in claim 14, wherein the connecting members are circumferentially expandible.

16. The intravascular tubular stent as claimed in claim 14, wherein the connecting members are longitudinally expandible.

25 17. The intravascular tubular stent as claimed in claim 1, wherein adjacent rings are connected by connecting mechanisms disposed to expand into the largest gaps produced between said rings upon radial expansion.

18. The intravascular tubular stent as claimed in claim 17, wherein the connecting mechanisms limit the longitudinal and/or radial expansion of the stent.

19. The intravascular tubular stent as claimed in claim 17, wherein the connecting mechanisms extend between a portion of an extendable element of one ring and a portion of a non-adjacent extendable element of an adjacent ring.

5 20. The intravascular tubular stent as claimed in claim 7, wherein at least one interconnecting member extends between a portion of one ring and an adjacent portion of an adjacent ring.

21. The intravascular tubular stent as claimed in claim 20, wherein said connecting member is disposed at substantially the same diagonal orientation as the elongate openings of the functional unit.

10 22. The intravascular tubular stent as claimed in claim 1, wherein radial expansion of said stent results in substantially no shortening in the length of said stent.

23. An intravascular tubular stent expandable between a first, constricted state and a second state of greater expanded diameter; said stent comprising in its constricted state:

15 a plurality of radially expandable rings each formed of a plurality of circumferentially extendable elements, each circumferentially extendable element comprising one or more U-shaped elements having a bendable joint from which a pair of arms extend generally parallelly, said arms defining therebetween a generally constant width opening which opens away from said bendable joint, said constant width opening being arranged in a diagonal orientation with respect to the longitudinal axis of the stent; and

20 each pair of adjacent radially expandable rings being connected to each other at at least one location.

24. The intravascular tubular stent as claimed in claim 23, wherein said extendable element includes one or more functional units having a bendable joint from which a pair of arms extend, said arms converging toward their ends distal the bendable joint so as to form an elongate converging opening therebetween, said functional units being arranged such that the
25 elongate openings are disposed generally diagonally with respect to the longitudinal axis of the tubular stent.

25. The intravascular tubular stent as claimed in claim 23, wherein each expandable ring is substantially identical to each adjacent ring.

26. The intravascular tubular stent as claimed in claim 23, wherein each expandable ring is the mirror-image in the axial direction to each adjacent ring.

27. The intravascular tubular stent as claimed in claim 23, wherein each expandable ring is disposed obliquely with respect to the longitudinal axis of the stent.

5 28. The intravascular tubular stent as claimed in claim 23, wherein circumferentially adjacent extendable elements are connected by radially expansible connection means.

29. The intravascular tubular stent as claimed in claim 28, wherein the radially expansible connection means comprises a U-shaped connector having a pair of arms between which a constant width opening is defined.

10 30. The intravascular tubular stent as claimed in claim 29, wherein said constant width opening of said U-shaped connector is disposed substantially parallel to the longitudinal axis of said stent.

15 31. The intravascular tubular stent as claimed in claim 29, wherein said constant width opening of said U-shaped connector is disposed substantially perpendicular to the constant width opening of the U-shaped element.

32. The intravascular tubular stent as claimed in claim 28, wherein said radially expansible connection means comprises a functional unit having a bendable joint from which a pair of arms extend, said arms converging toward their ends distal the bendable joint so as to form an elongate converging opening therebetween.

20 33. The intravascular tubular stent as claimed in claim 32, whereby the elongate converging opening is disposed substantially parallel to the longitudinal axis of said stent.

34. The intravascular tubular stent as claimed in claim 32, whereby the elongate converging opening is disposed diagonally with respect to the longitudinal axis of said stent.

25 35. The intravascular tubular stent as claimed in claim 23, wherein at least one interconnecting member extends between a portion of one ring and an adjacent portion of an adjacent ring.

36. The intravascular tubular stent as claimed in claim 35, wherein the at least one interconnecting member extends between a bendable joint of one U-shaped element to a bendable joint of another U-shaped element in an adjacent ring.

37. The intravascular tubular stent as claimed in claim 36, wherein said one extendable element is longitudinally adjacent the another extendable element in the adjacent ring.

38. The intravascular tubular stent as claimed in claim 35, wherein said at least one interconnecting member extends between one of a plurality of connecting members disposed between circumferentially adjacent extendable elements of one ring to one of another plurality of connecting members disposed between circumferentially adjacent extendable elements of an adjacent ring.

39. The intravascular tubular stent as claimed in claim 38, wherein the connecting members are circumferentially expansible.

40. The intravascular tubular stent as claimed in claim 38, wherein the connecting members are longitudinally expansible.

41. The intravascular tubular stent as claimed in claim 23, wherein radial expansion of said stent results in substantially no shortening in the length of said stent.

42. A self-compensating, radially expandable tubular stent comprising:

a plurality of interconnected radially expandable rings each formed of a plurality of circumferentially extendable elements each consisting of one or more over-parallel U-shaped elements having an elongate converging opening defined between converging arms thereof.

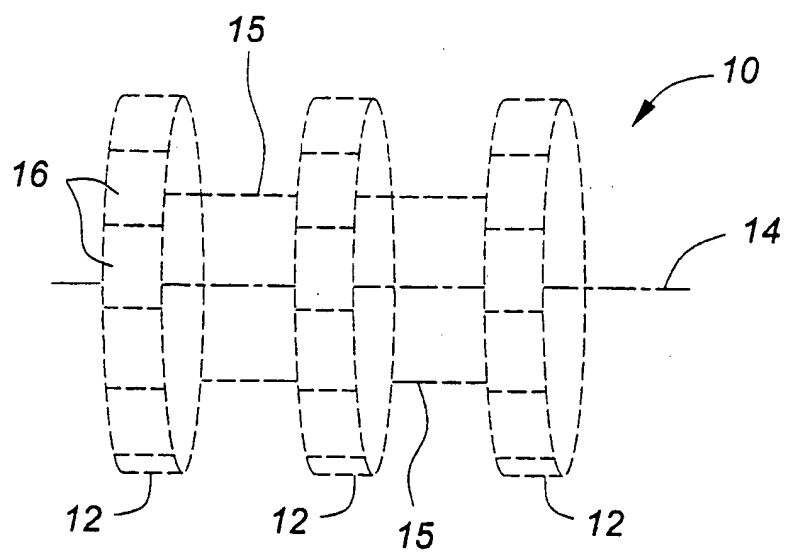
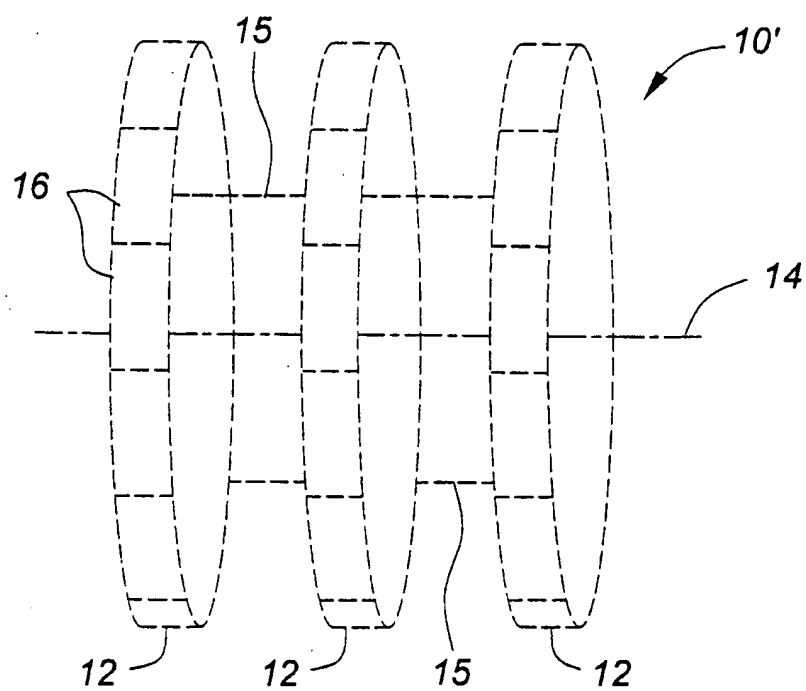
43. The self-compensating, radially expandable tubular stent as claimed in claim 42, wherein at least one of the one or more over-parallel U-shaped elements is disposed with its elongate converging opening oriented generally perpendicular to the longitudinal axis of the stent.

44. The self-compensating, radially expandable tubular stent as claimed in claim 42, wherein at least one of the one or more over-parallel U-shaped elements is disposed with its elongate converging opening oriented generally parallel to the longitudinal axis of the stent.

45. The self-compensating, radially expandable tubular stent as claimed in claim 42, wherein at least one of the one or more over-parallel U-shaped elements is disposed with its elongate converging opening oriented diagonally with respect to the longitudinal axis of the stent.

46. The self-compensating, radially expandable tubular stent as claimed in claim 42, wherein each extendable element is connected to an adjacent extendable element in a ring by a circumferentially extensible connector.
- 5 47. The self-compensating, radially expandable tubular stent as claimed in claim 46, wherein the extensible connector is a U-shaped connector having parallel arms defining a substantially constant width opening therebetween.
48. The self-compensating, radially expandable tubular stent as claimed in claim 47, wherein the constant width opening of the U-shaped connector is disposed in a substantially parallel orientation with respect to the longitudinal axis of the stent.
- 10 49. The self-compensating, radially expandable tubular stent as claimed in claim 47, wherein the constant width opening of the U-shaped connector is disposed in a diagonal orientation with respect to the longitudinal axis of the stent.
- 15 50. The self-compensating, radially expandable tubular stent as claimed in claim 46, wherein the extensible connector is an over-parallel U-shaped connector having converging arms defining a converging opening therebetween.
51. The self-compensating, radially expandable tubular stent as claimed in claim 50, wherein the converging opening of the over-parallel U-shaped connector is disposed in a substantially parallel orientation with respect to the longitudinal axis of the stent.
- 20 52. The self-compensating, radially expandable tubular stent as claimed in claim 50, wherein the converging opening of the over-parallel U-shaped connector is disposed in a diagonal orientation with respect to the longitudinal axis of the stent.
53. The self-compensating, radially expandable tubular stent as claimed in claim 42, wherein each expandable ring is disposed obliquely with respect to the longitudinal axis of the stent.
- 25 54. The self-compensating, radially expandable tubular stent as claimed in claim 42, wherein radial expansion of said stent results in substantially no shortening in the length of said stent.

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**FIG. 1A****FIG. 1B**

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FIG. 2A

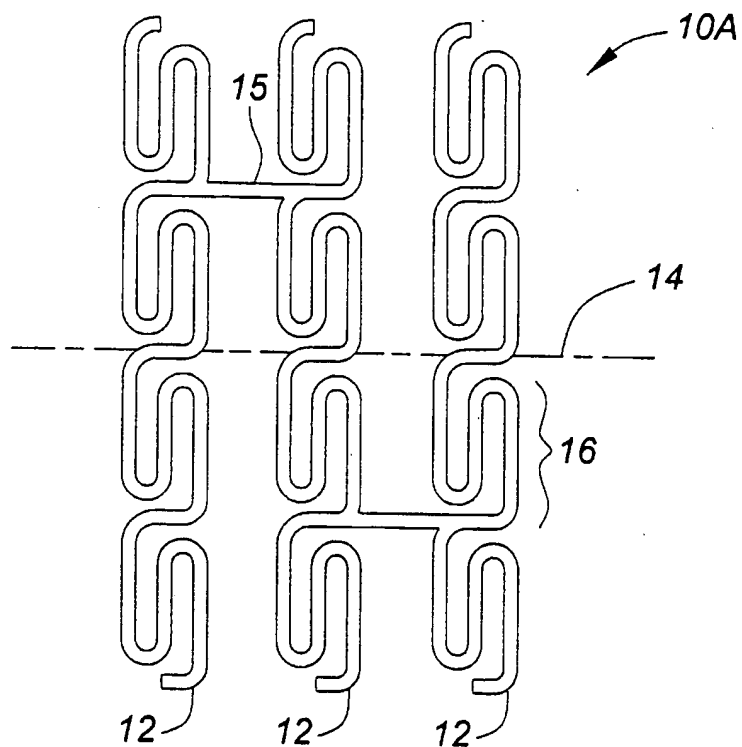
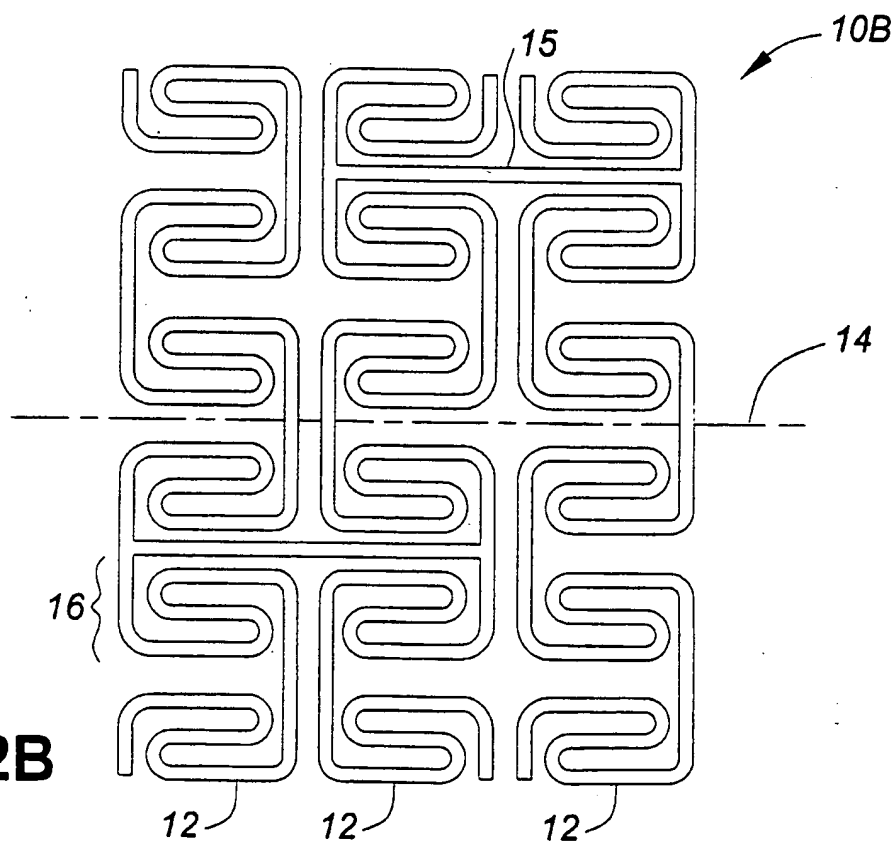
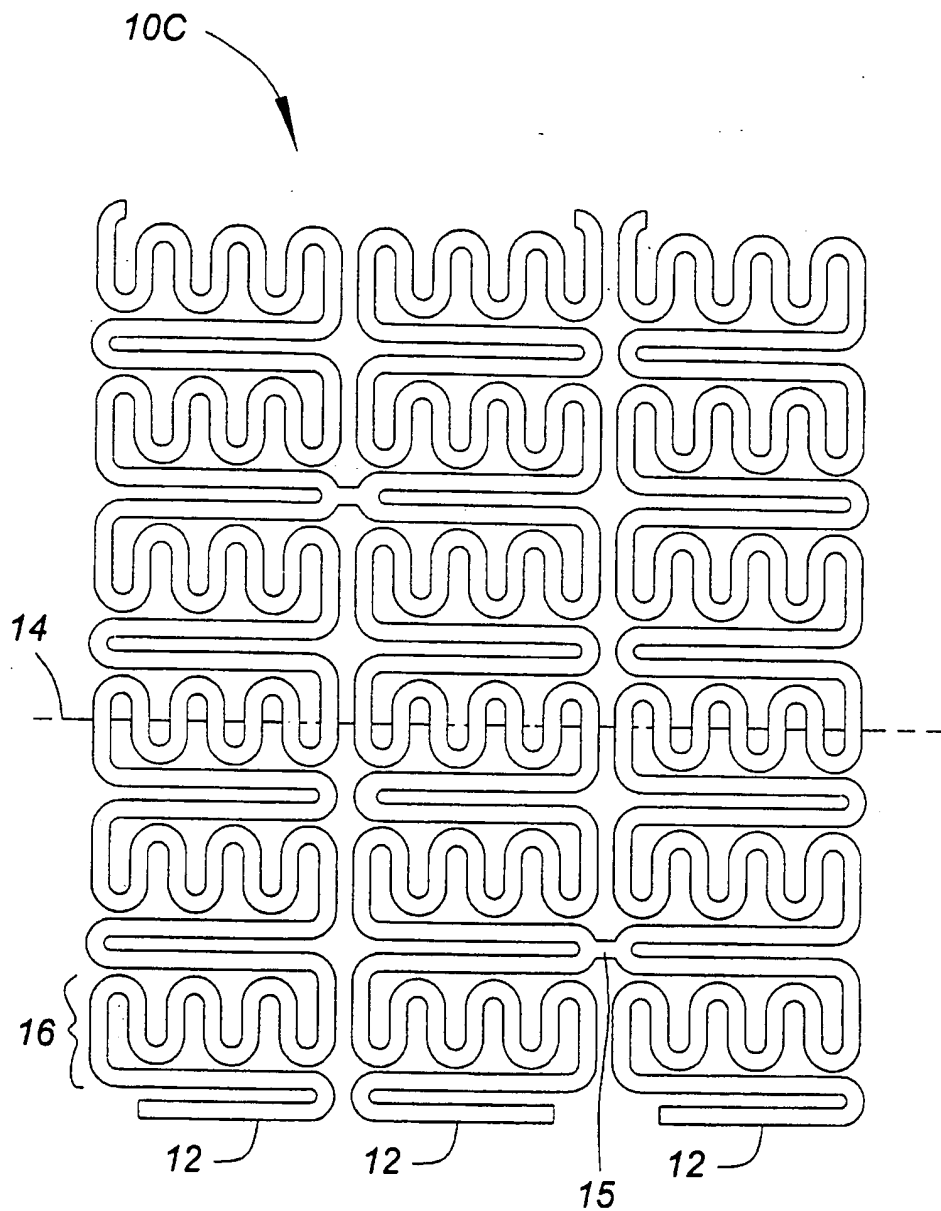


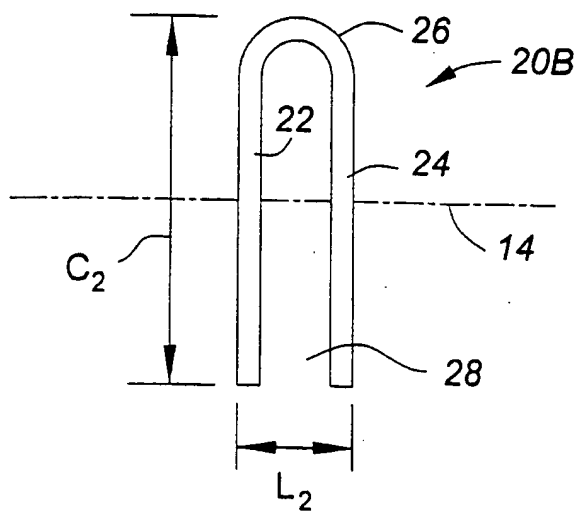
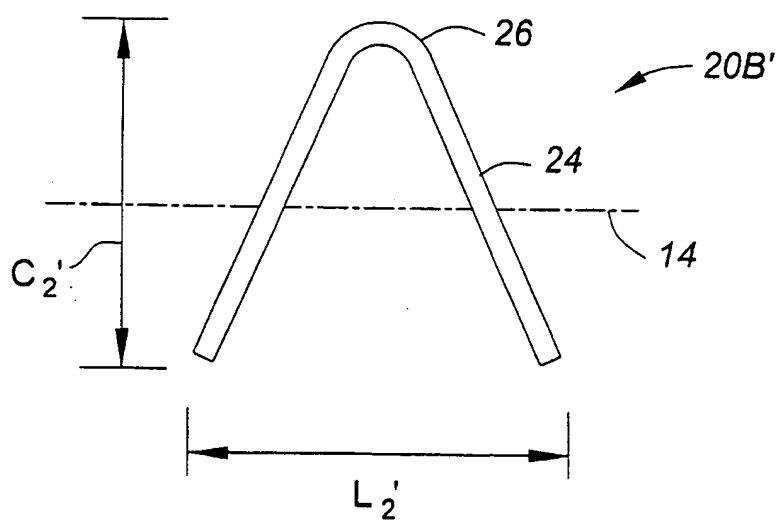
FIG. 2B



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**FIG. 2C**

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**FIG. 3A****FIG. 3B**

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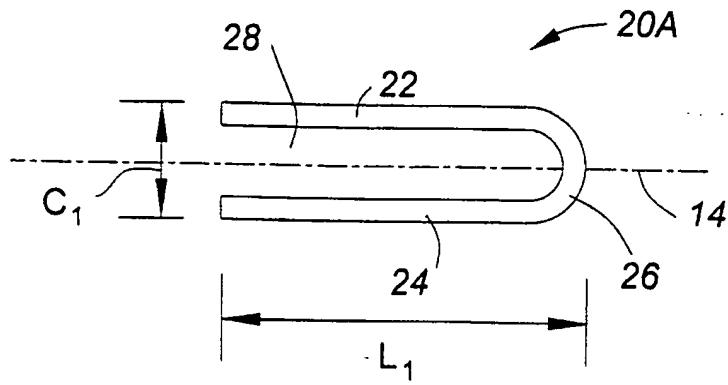


FIG. 3C

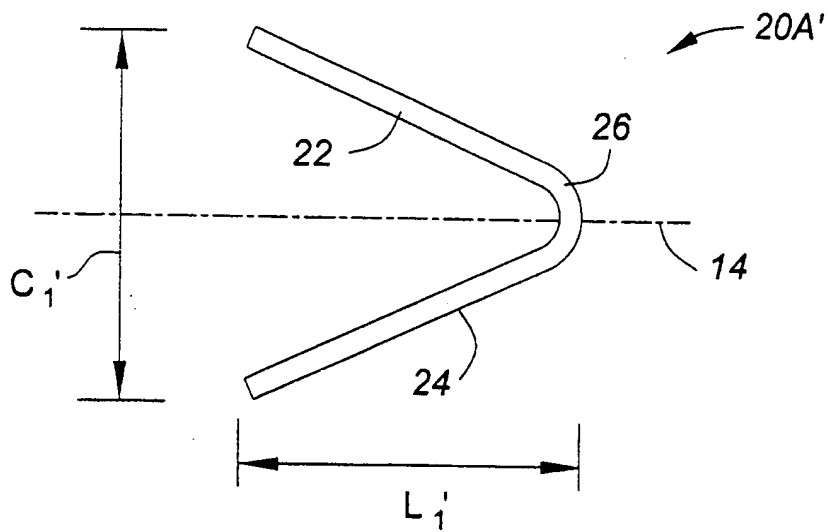
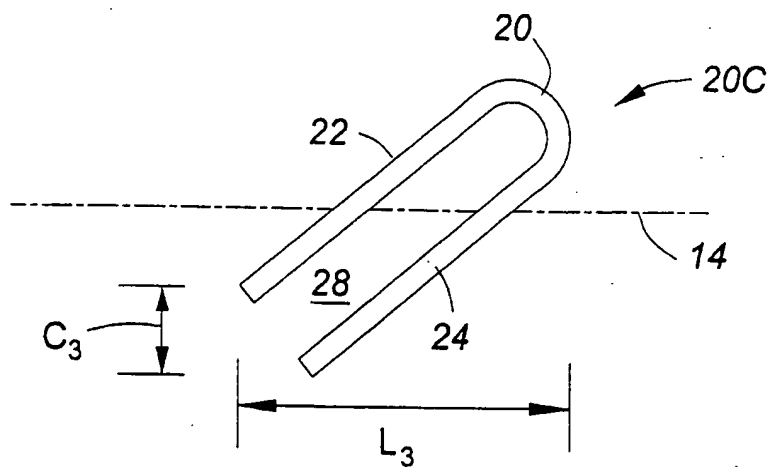
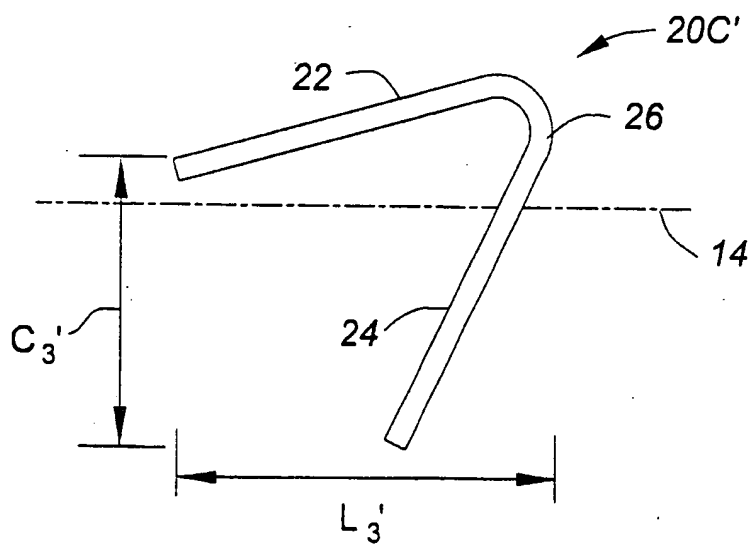
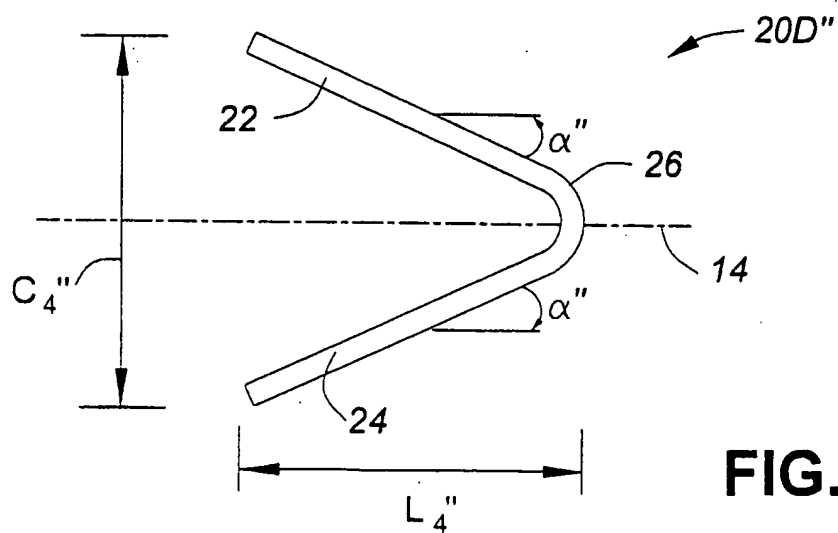
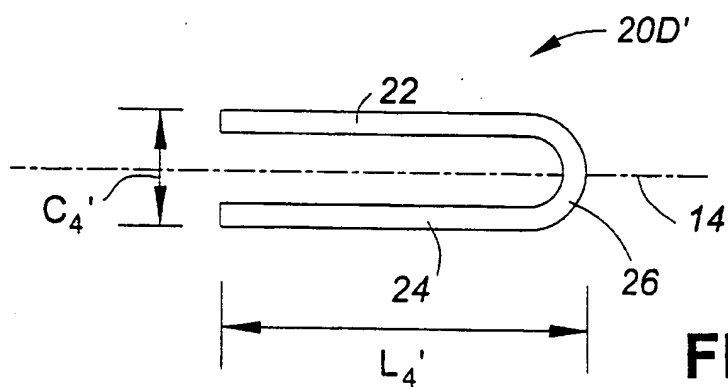
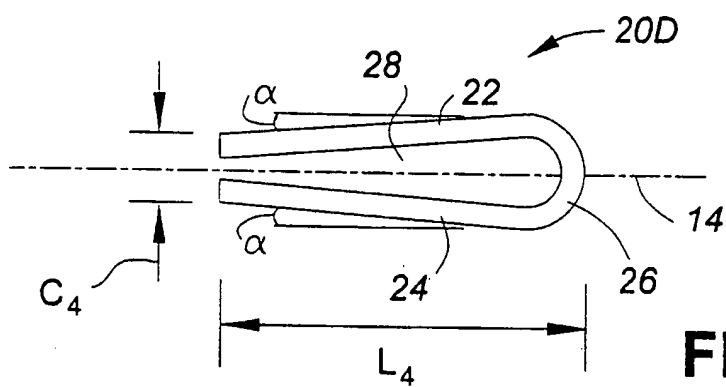


FIG. 3D

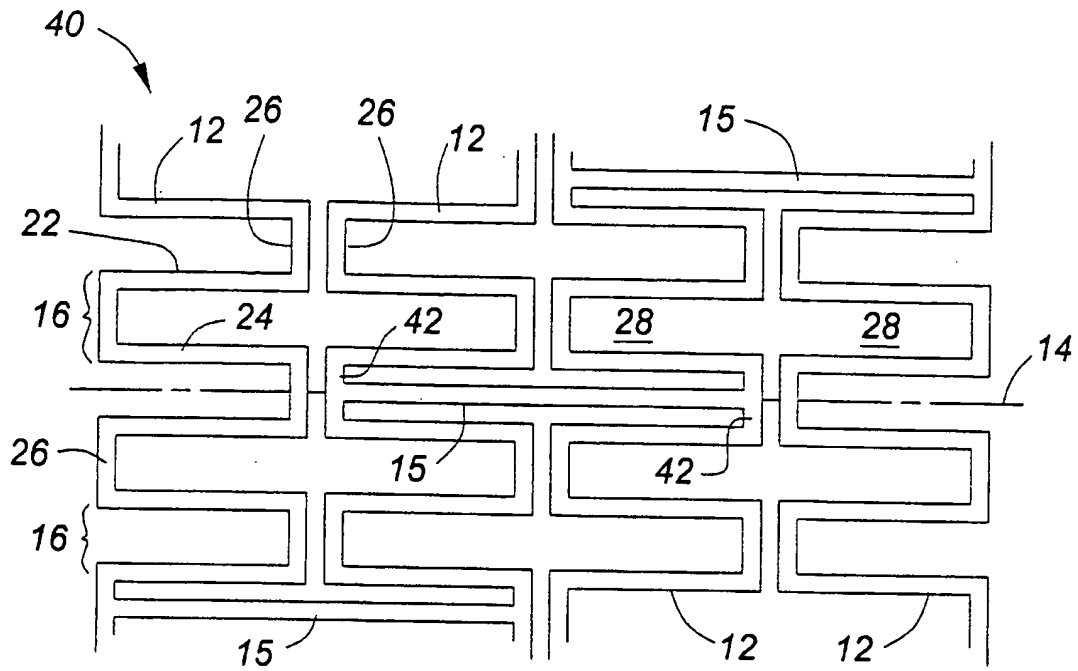
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**FIG. 3E****FIG. 3F**

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**FIG. 4A**

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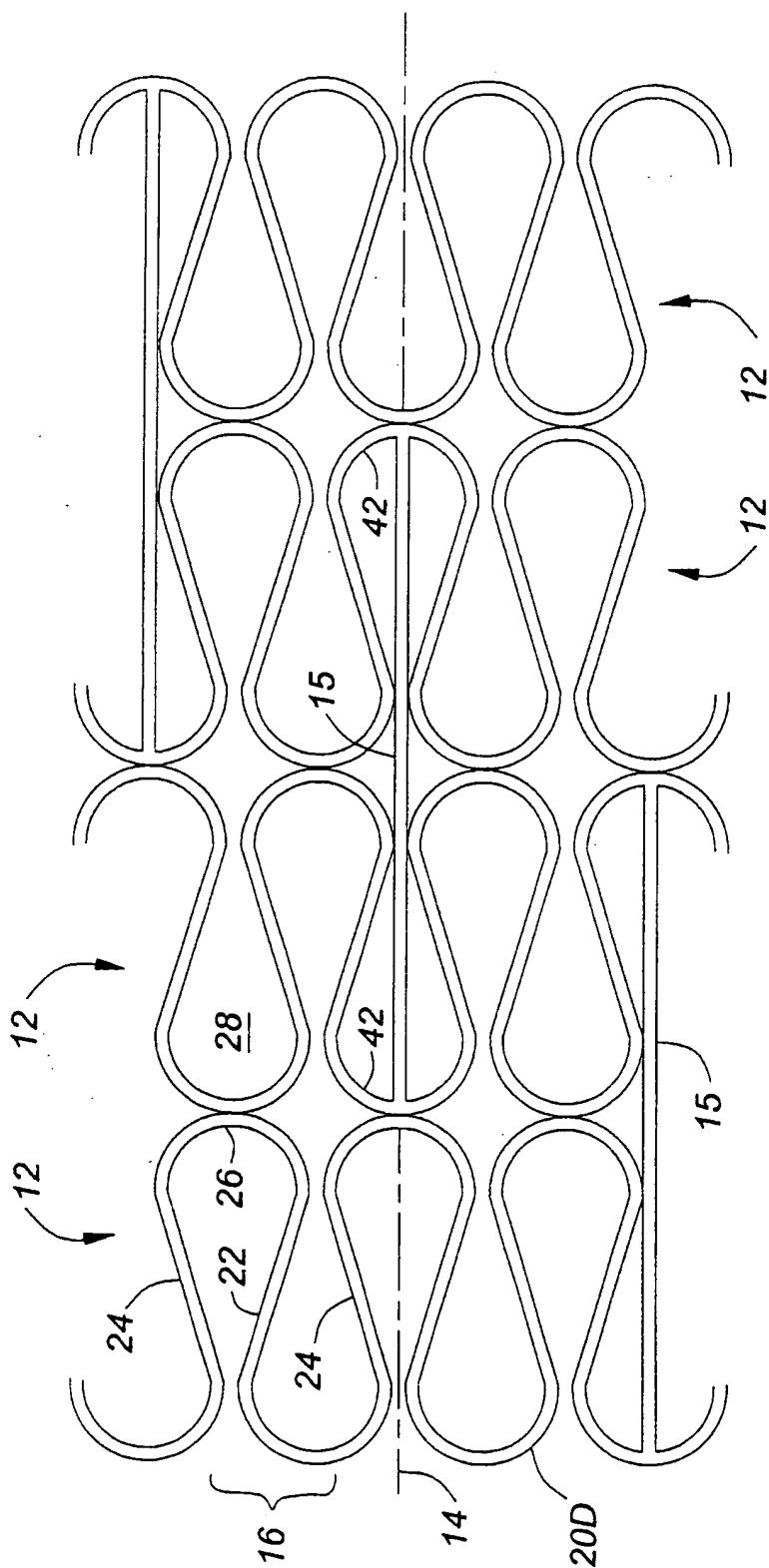


FIG. 4B

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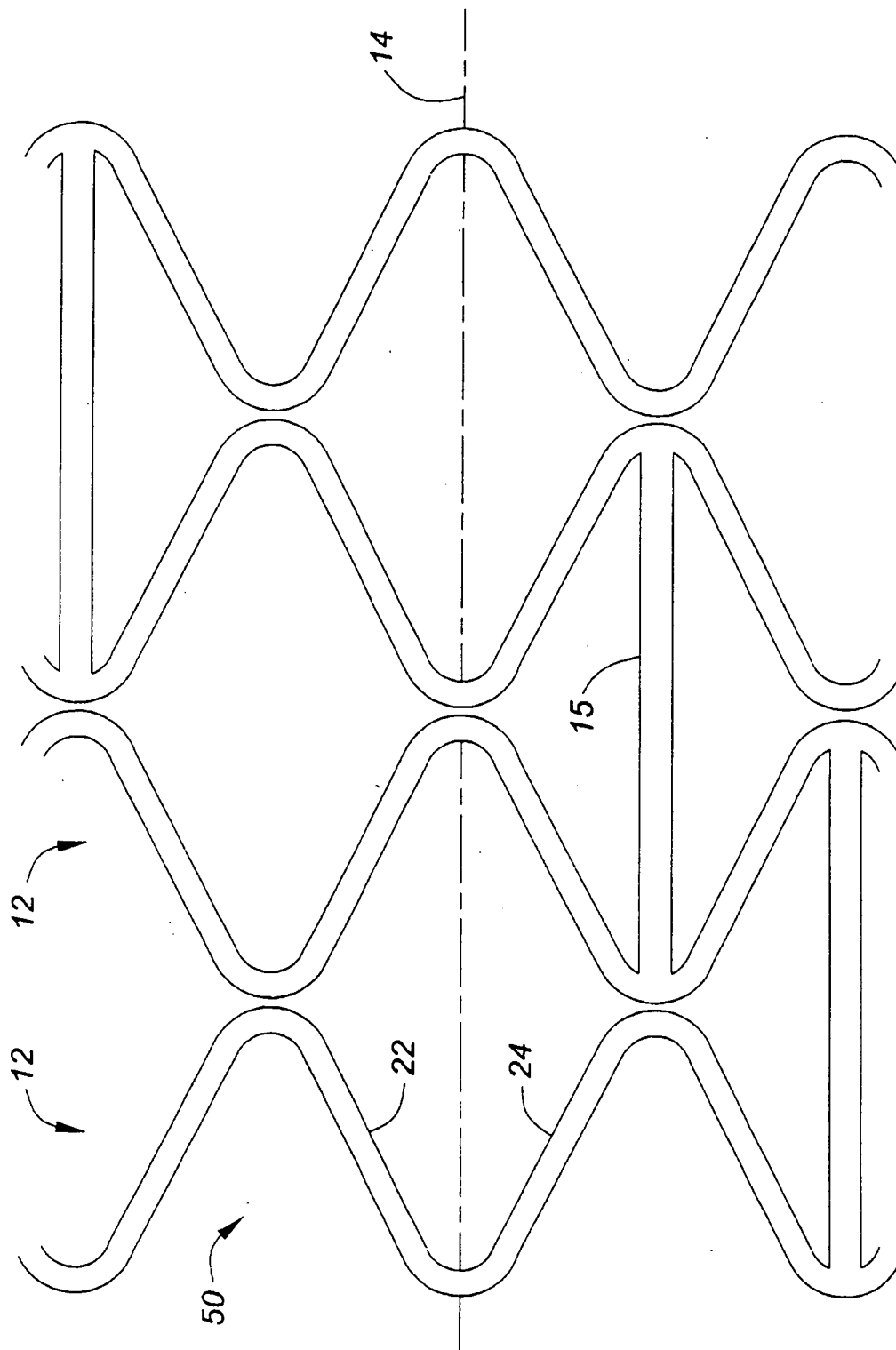


FIG. 4C

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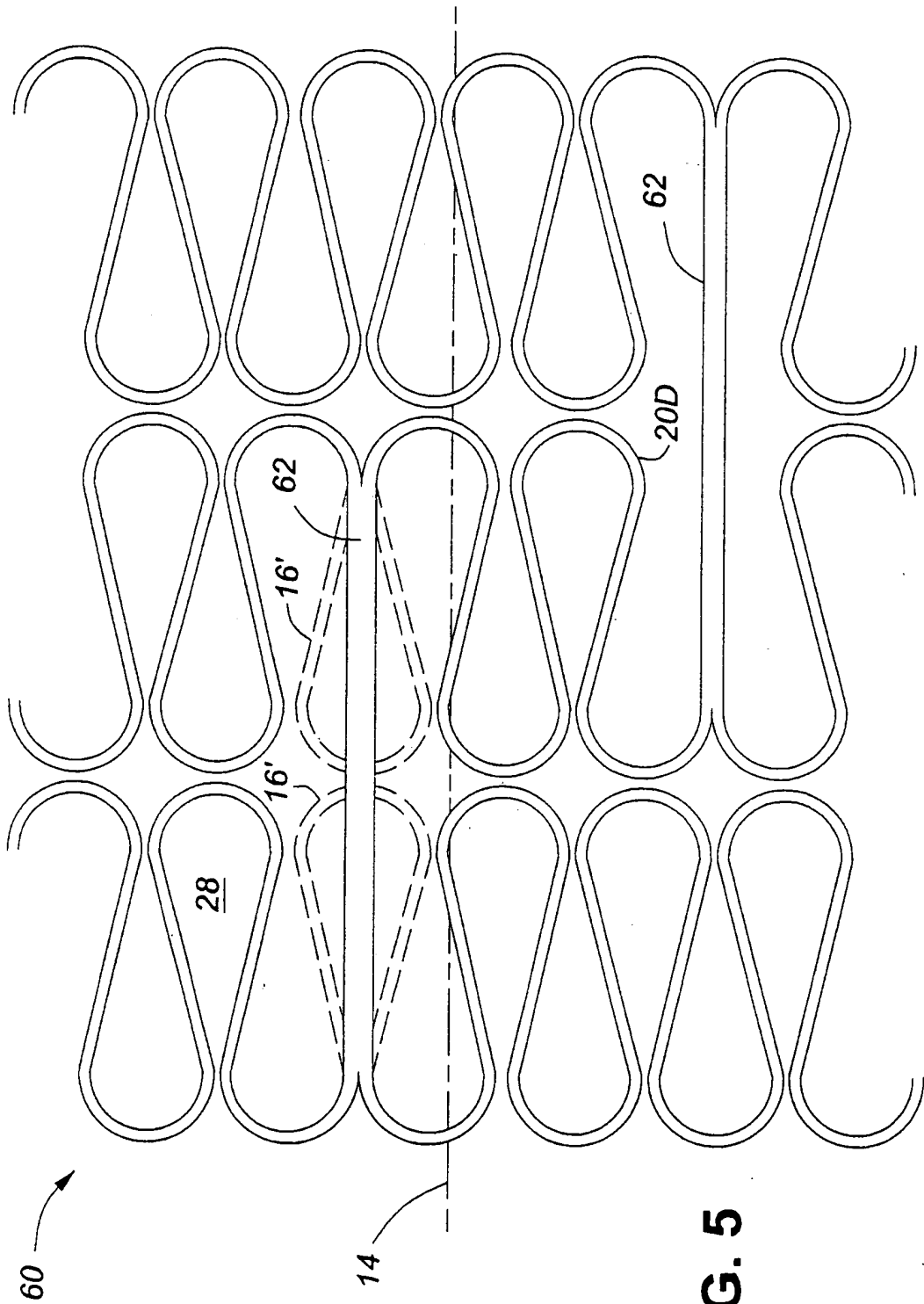


FIG. 5

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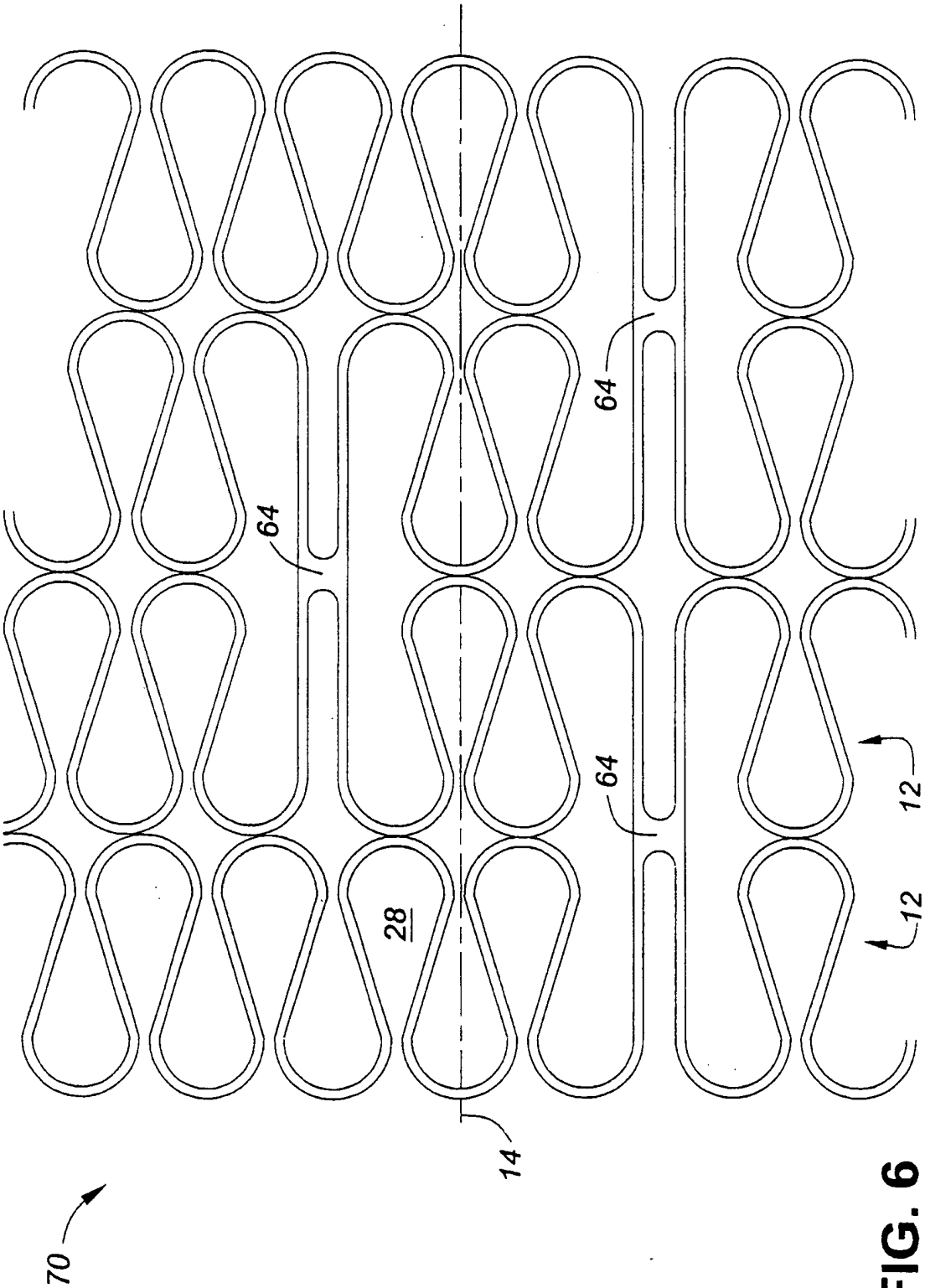
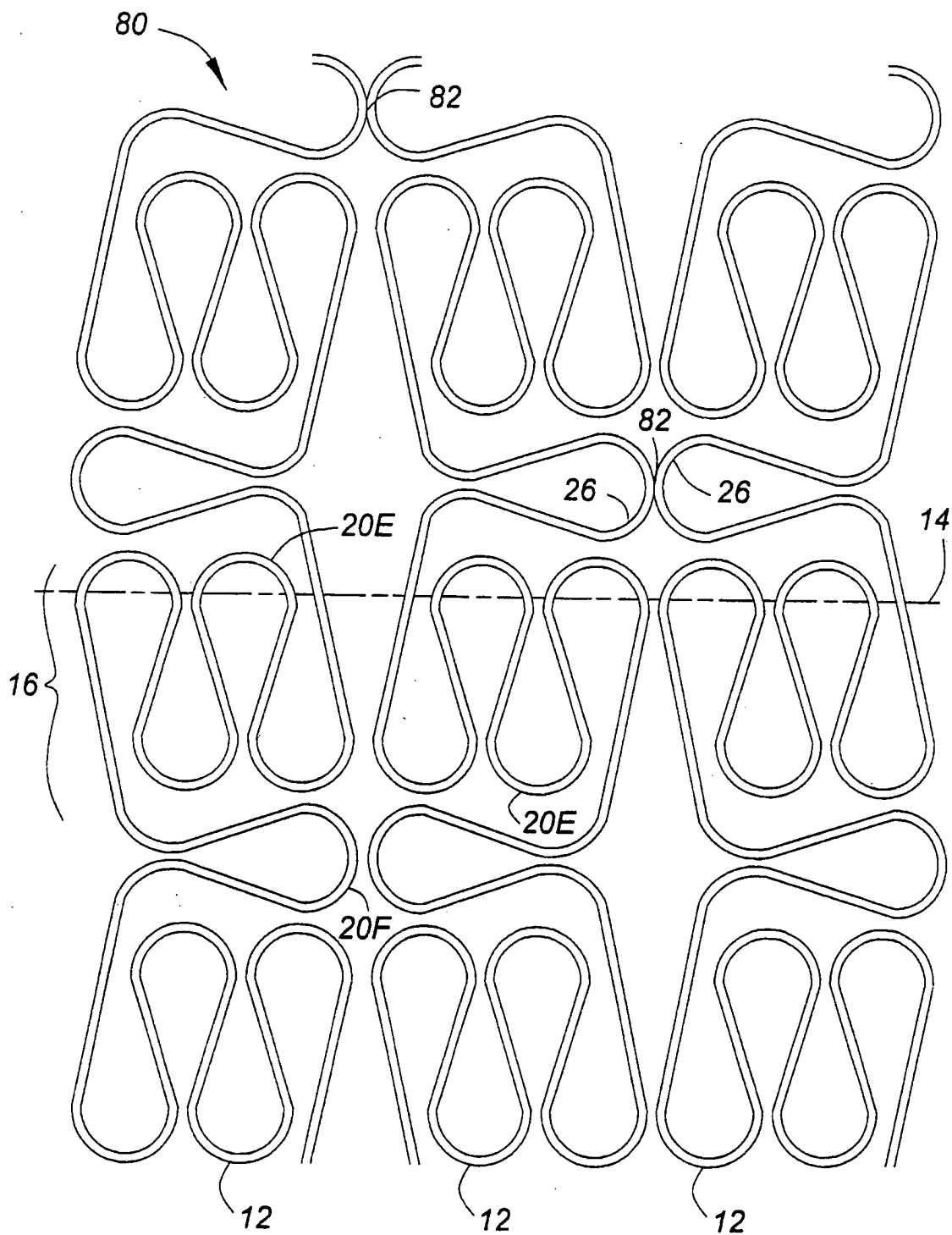


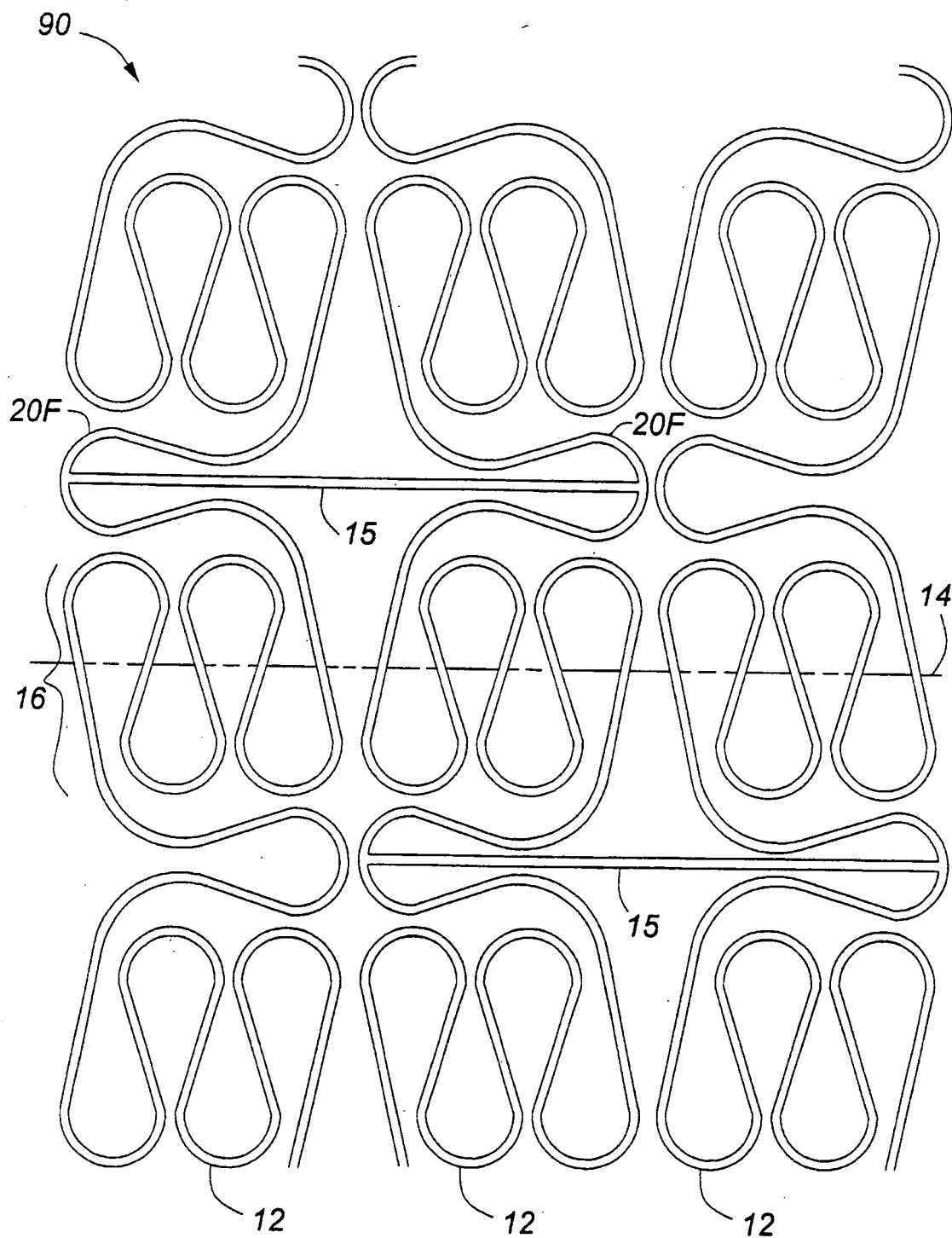
FIG. 6

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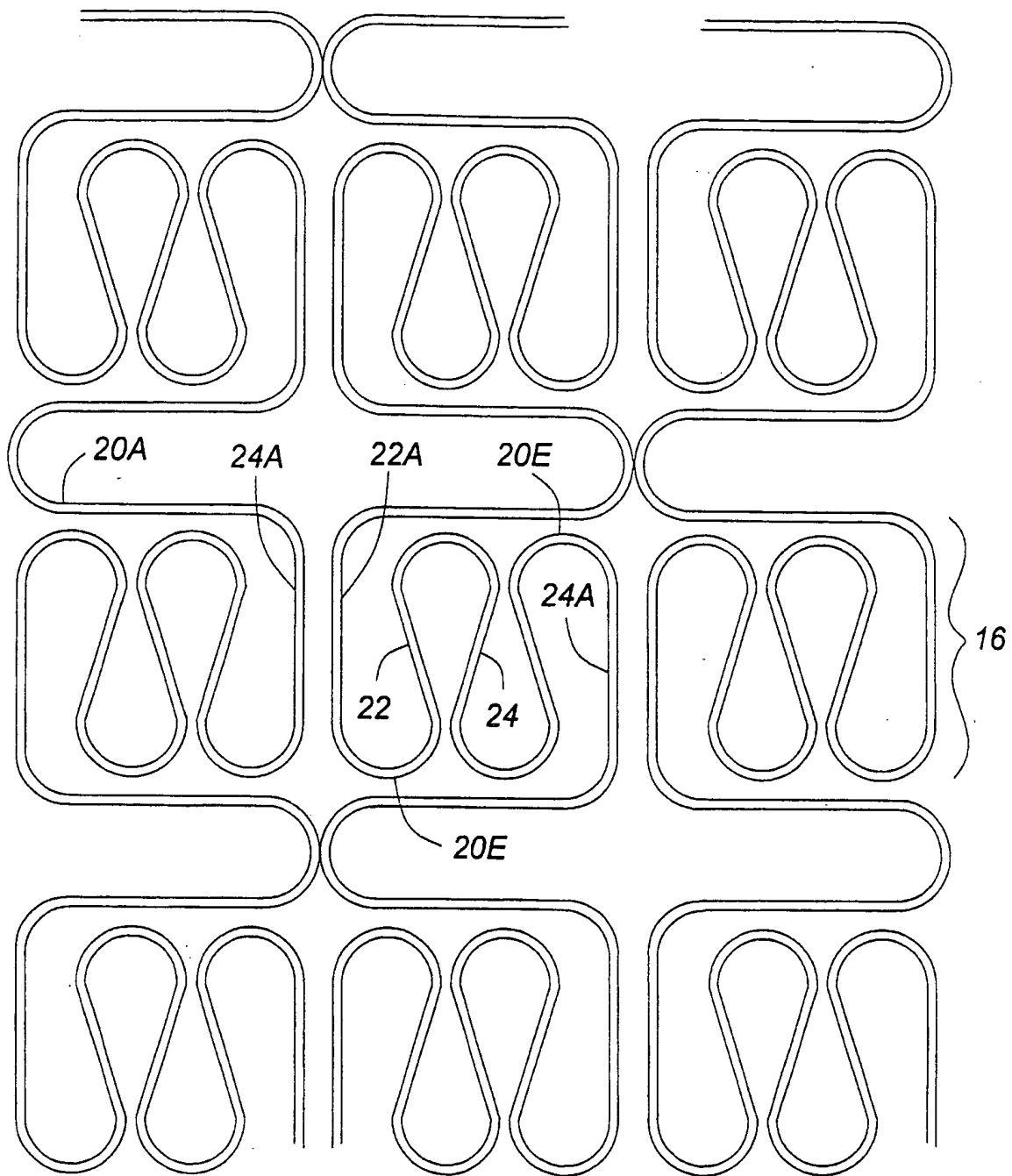
**FIG. 7**

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**FIG. 8**

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FIG. 9

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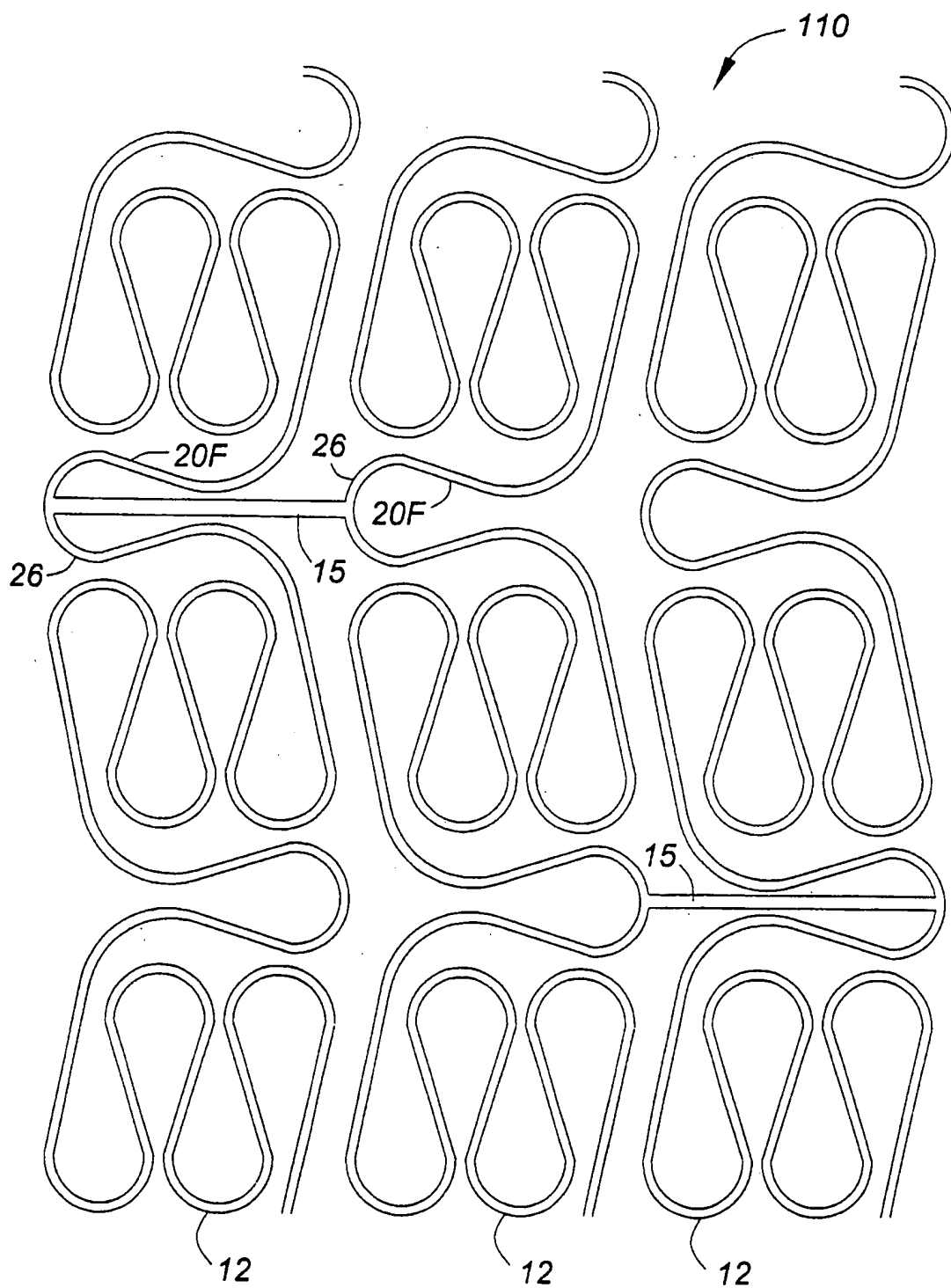
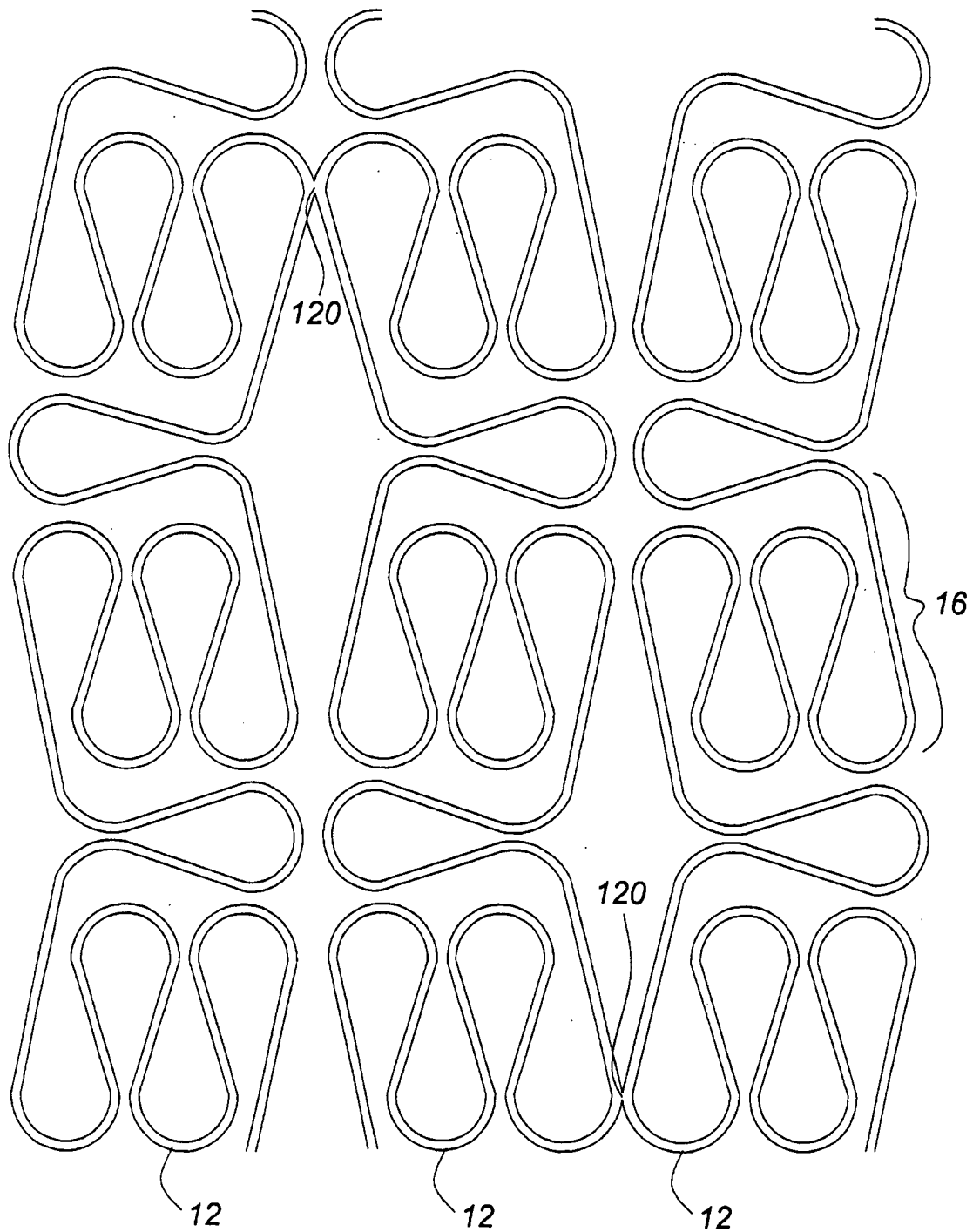


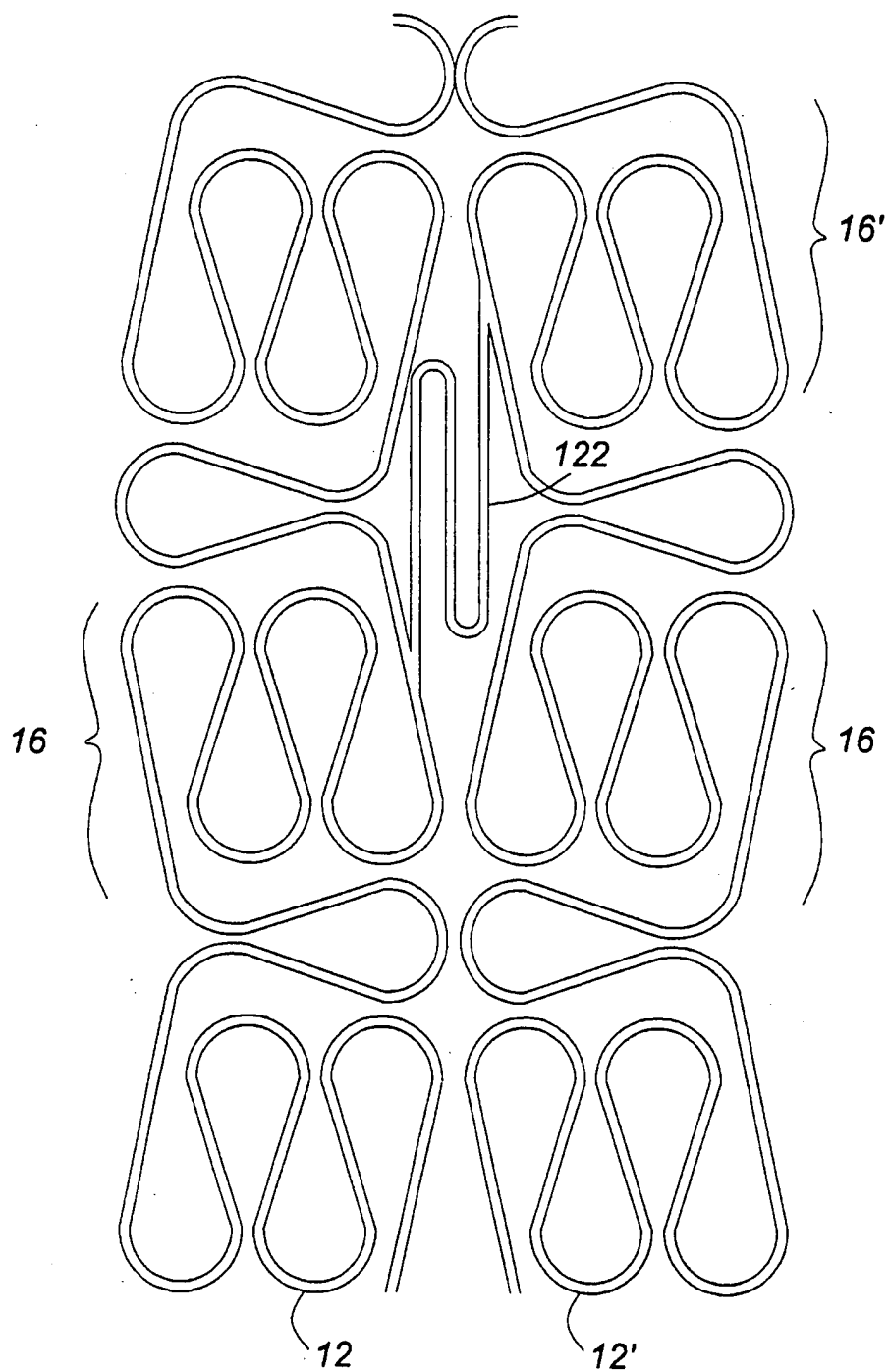
FIG. 10

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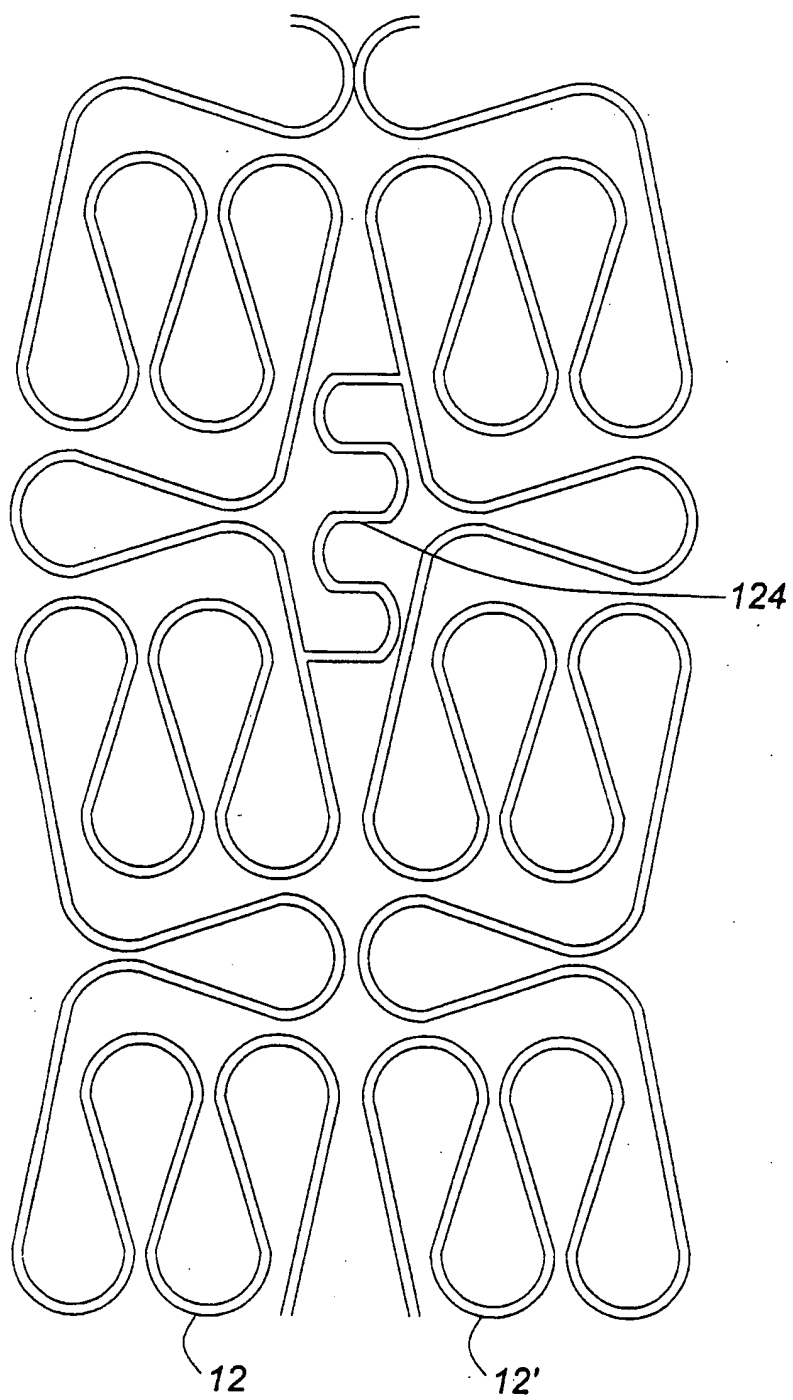
**FIG. 11**

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**FIG. 12**

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**FIG. 13**

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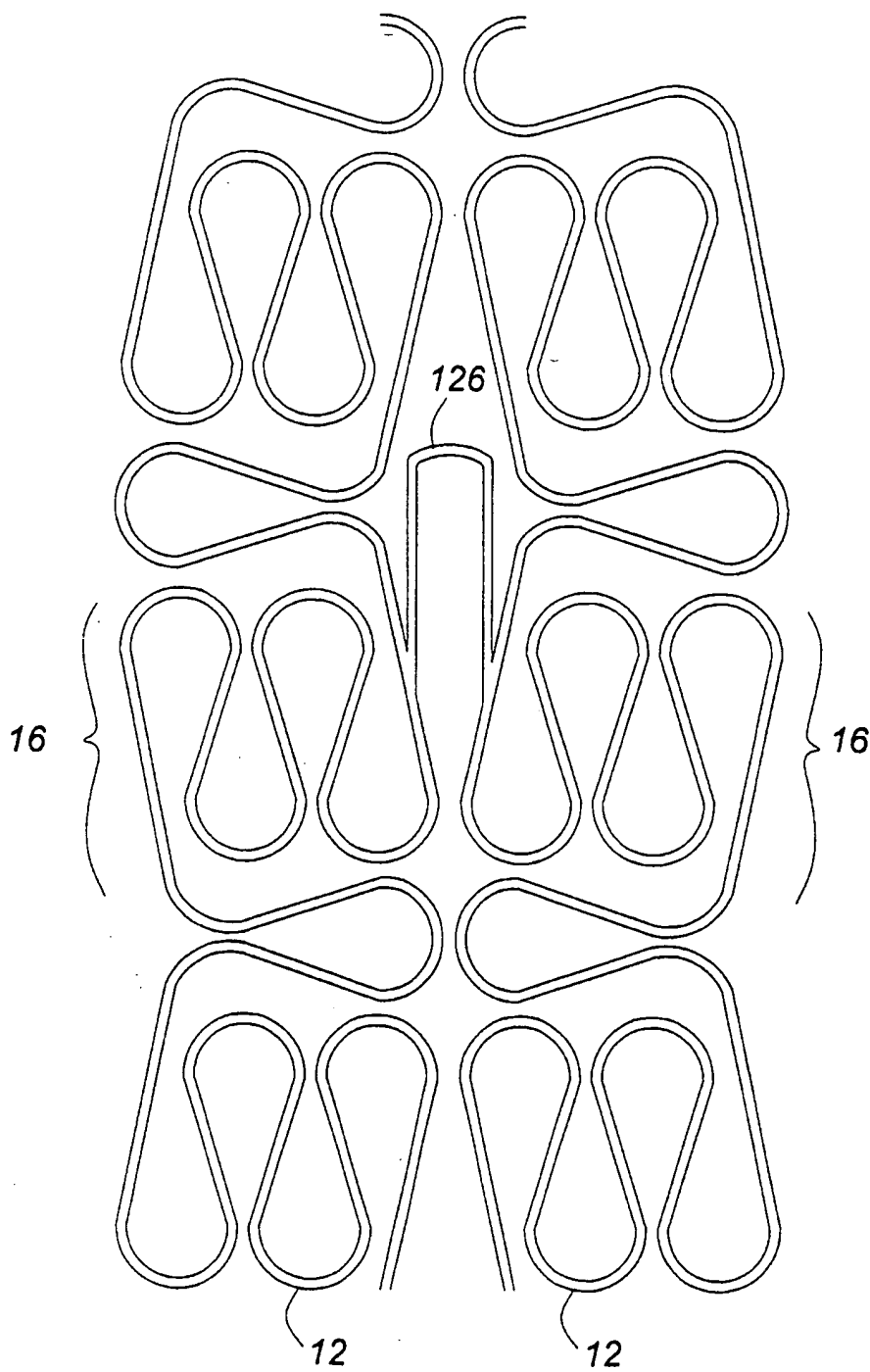
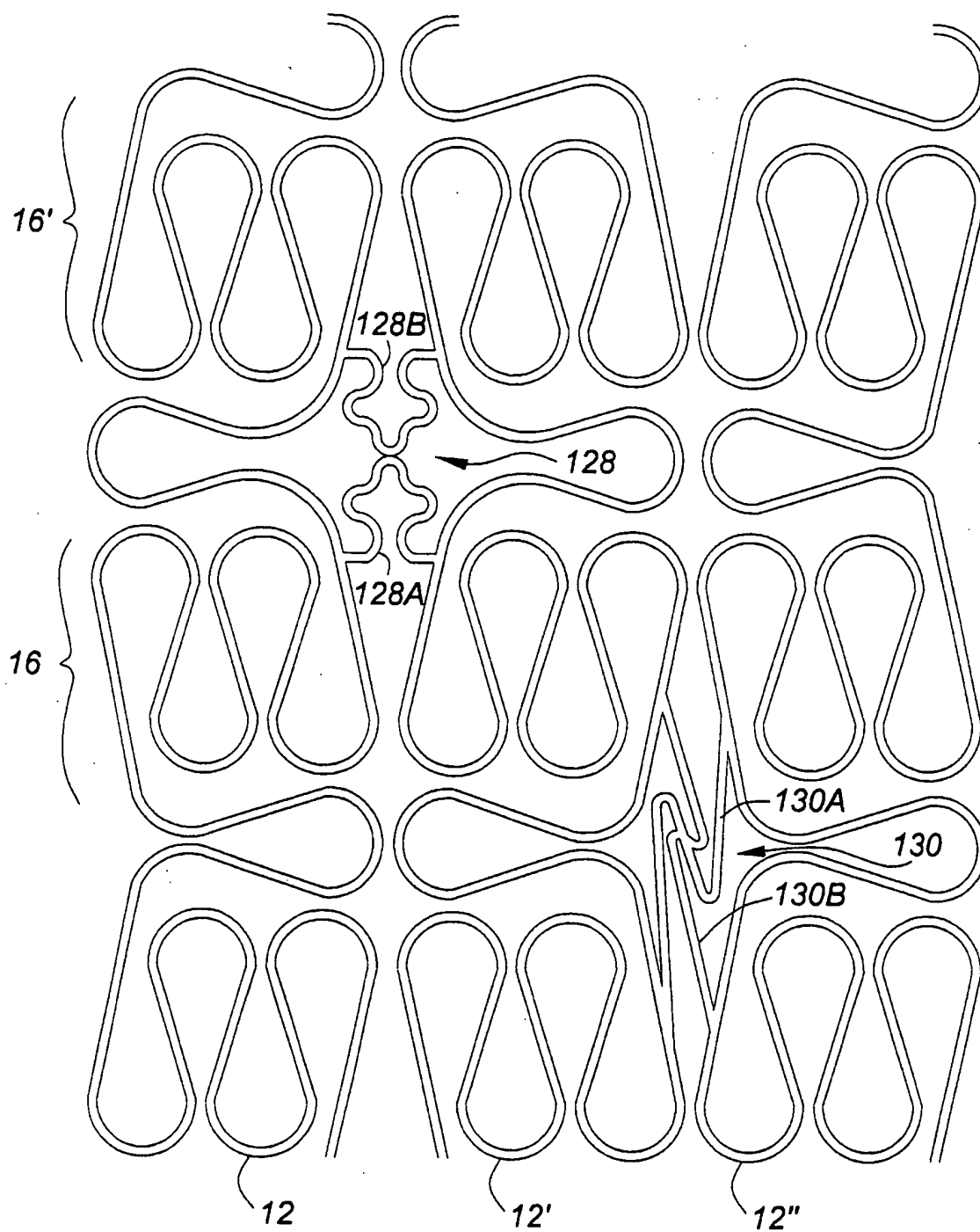


FIG. 14

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**FIG. 15**

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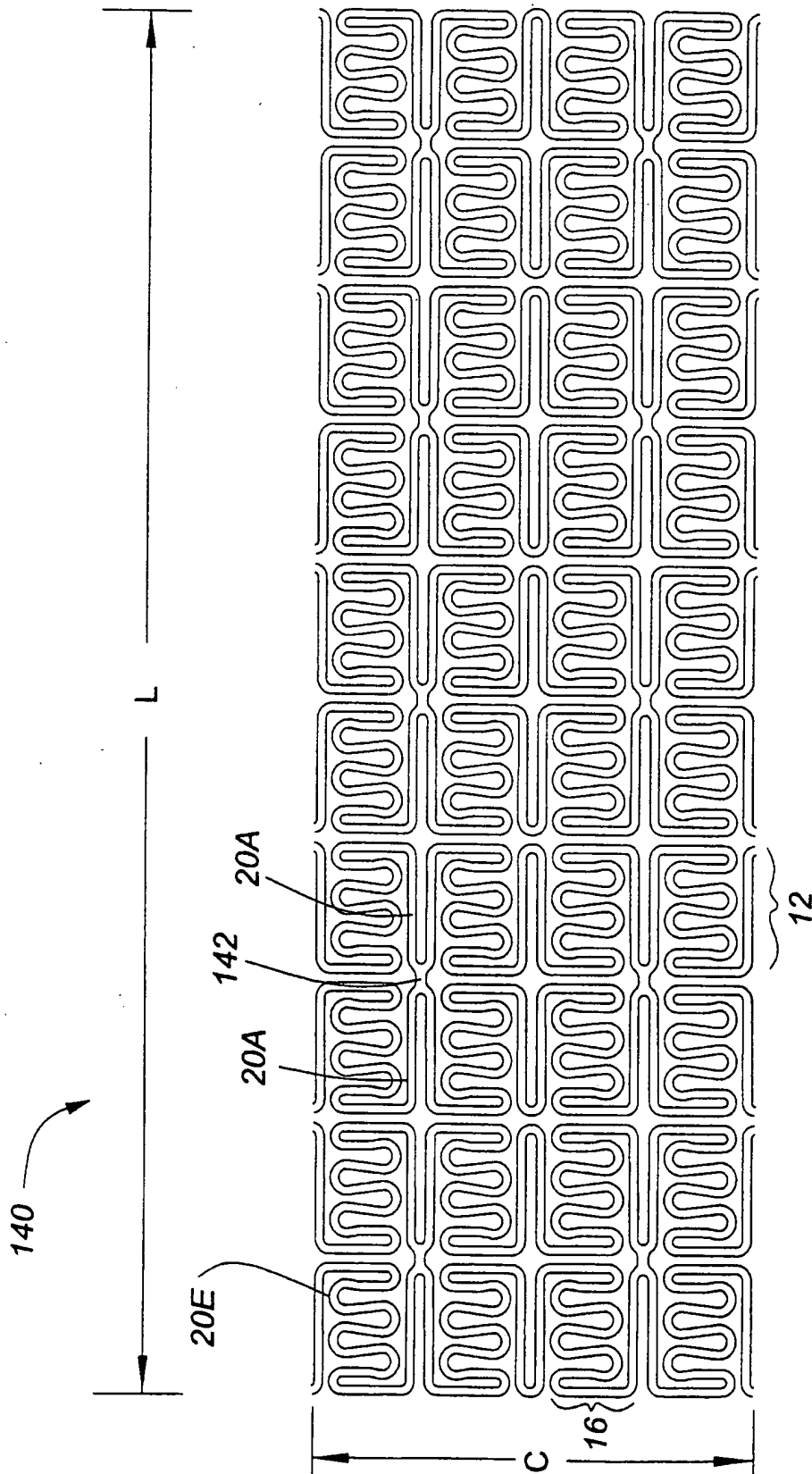


FIG. 16A

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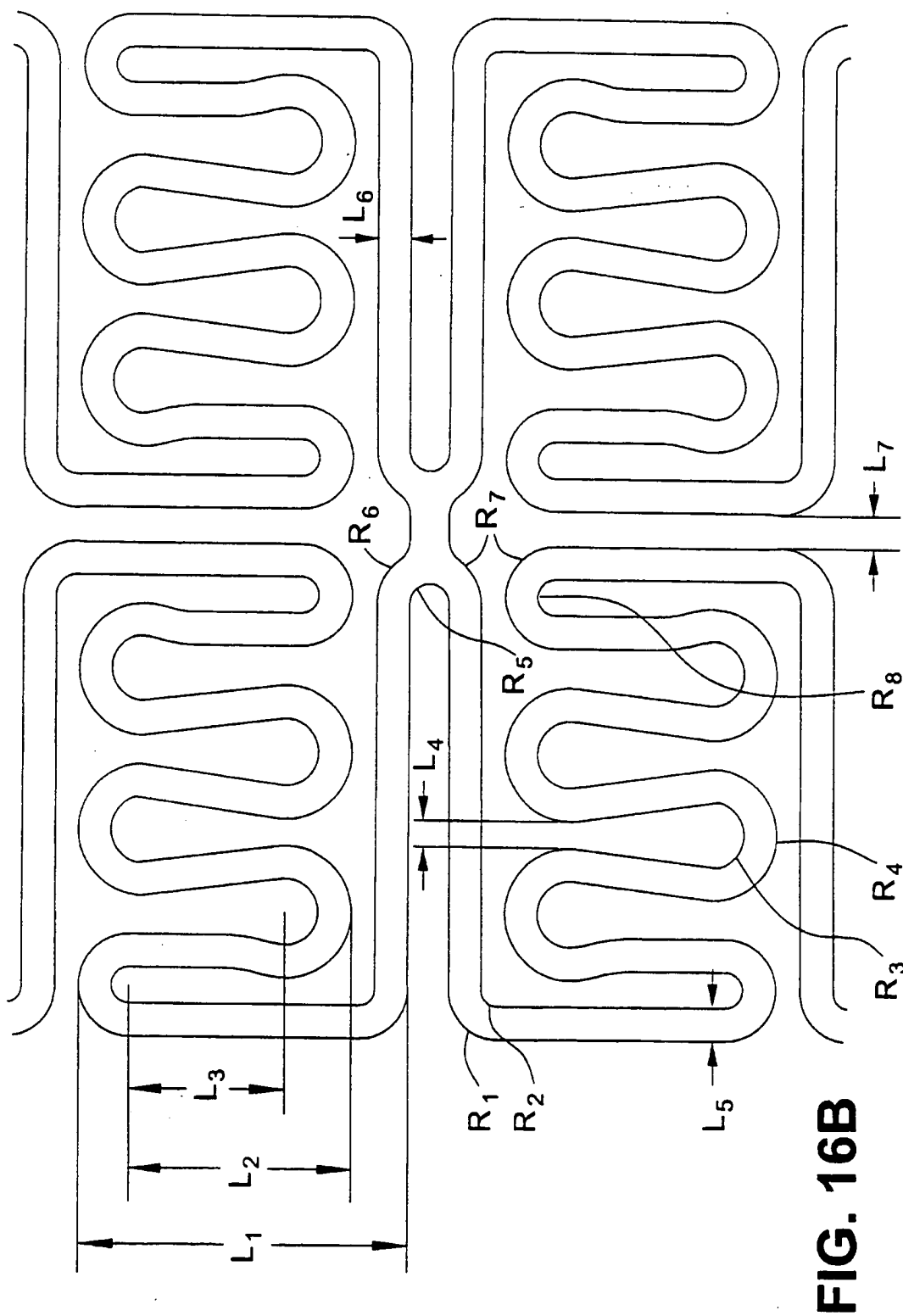
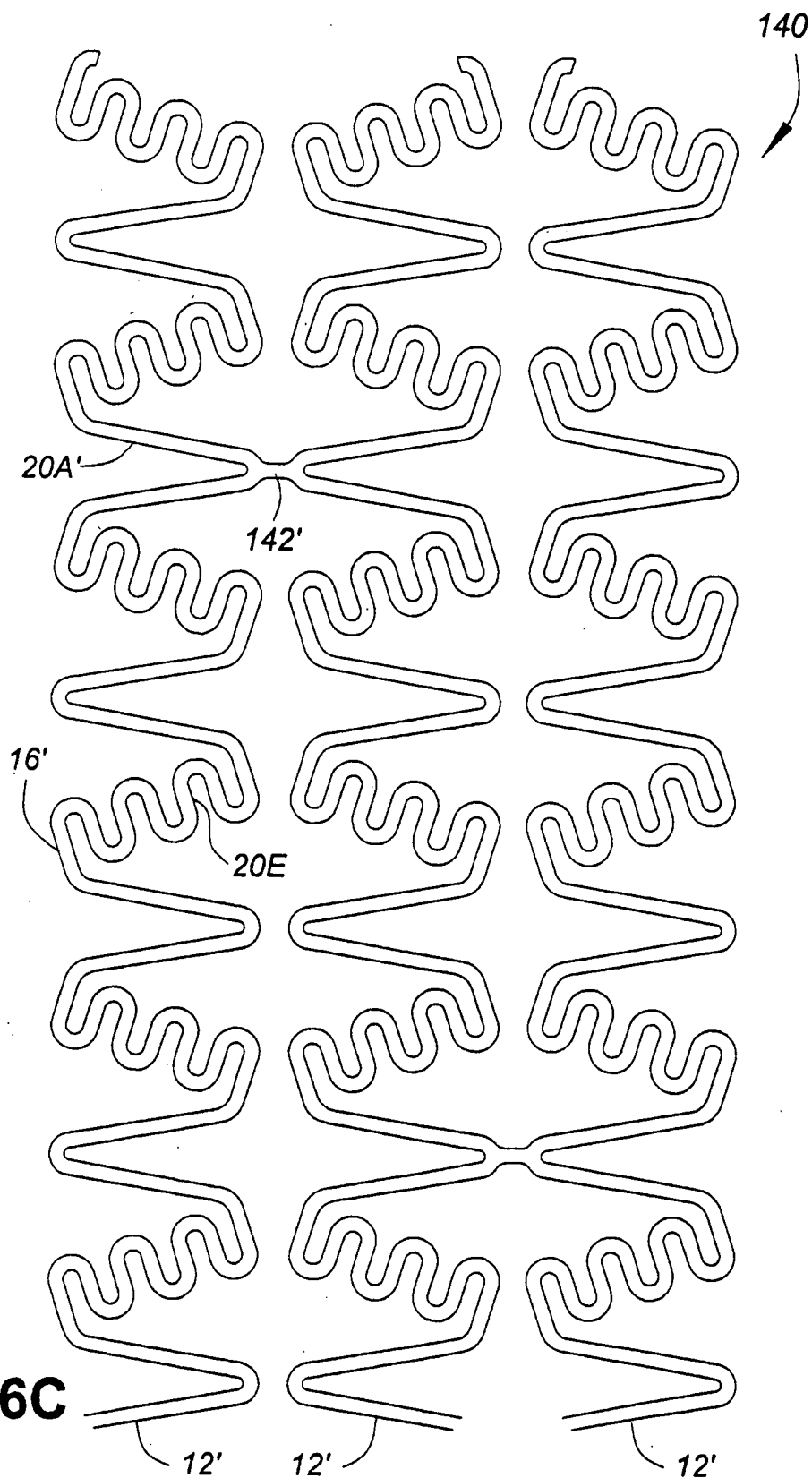
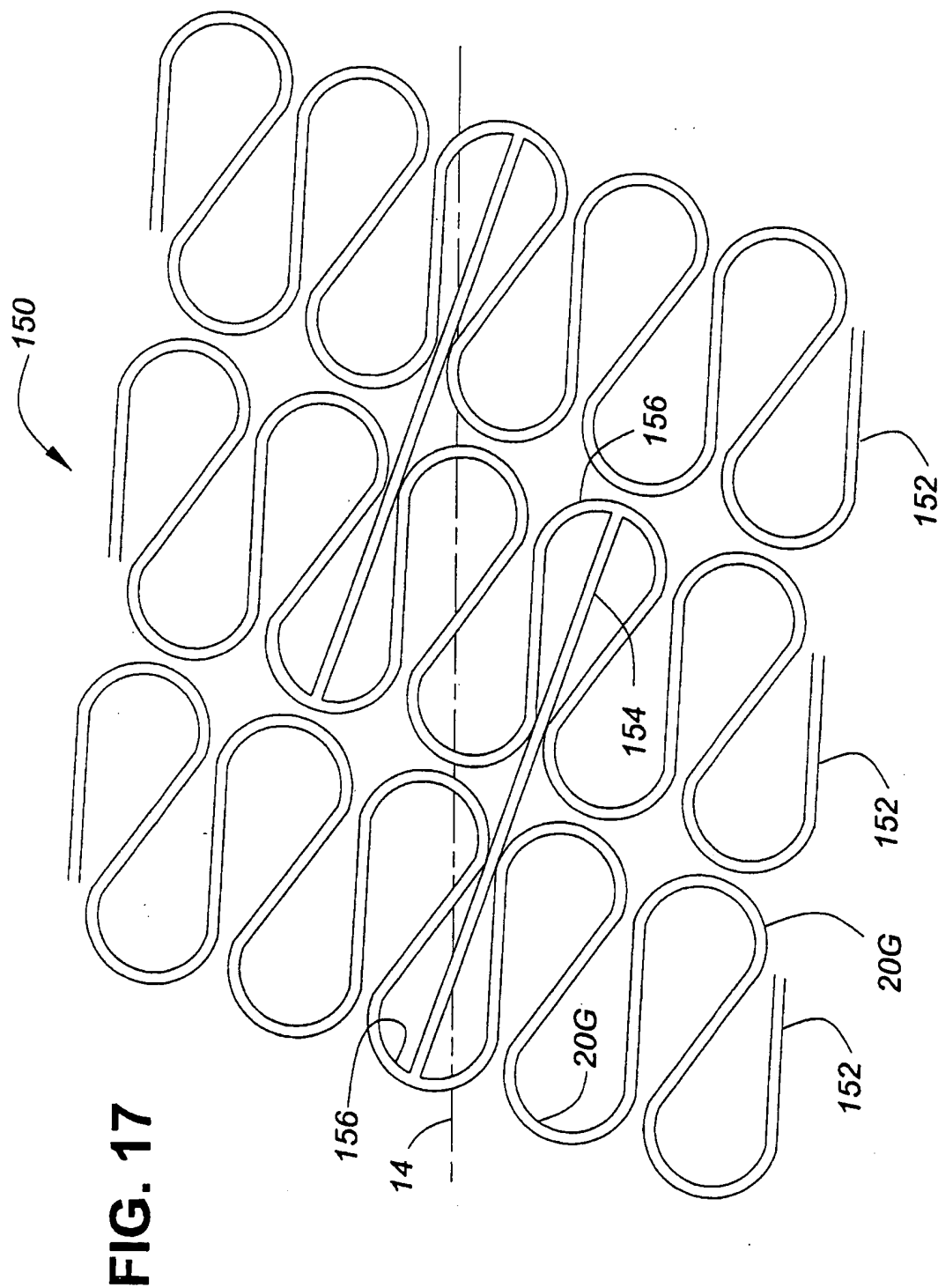


FIG. 16B

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**FIG. 16C**

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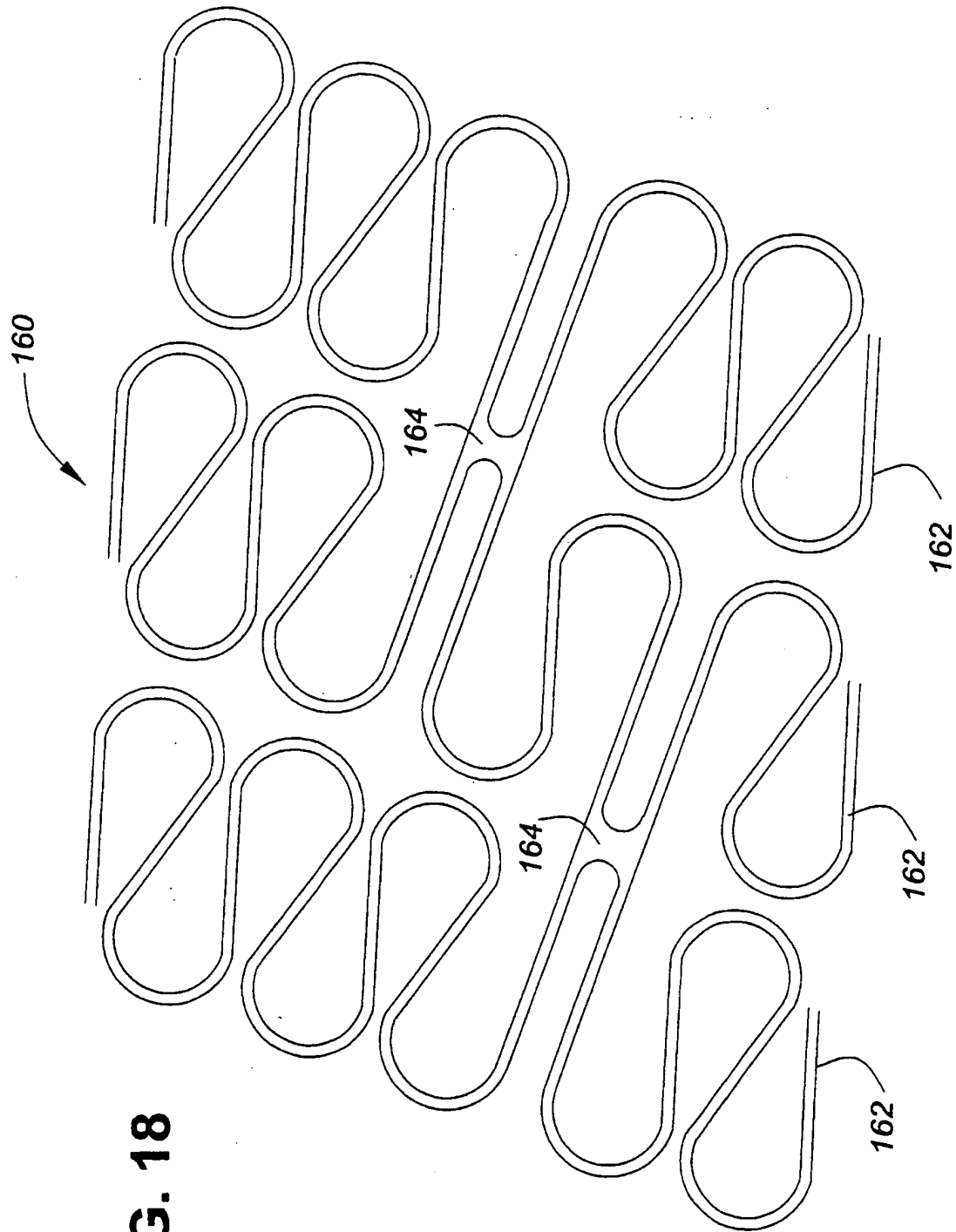
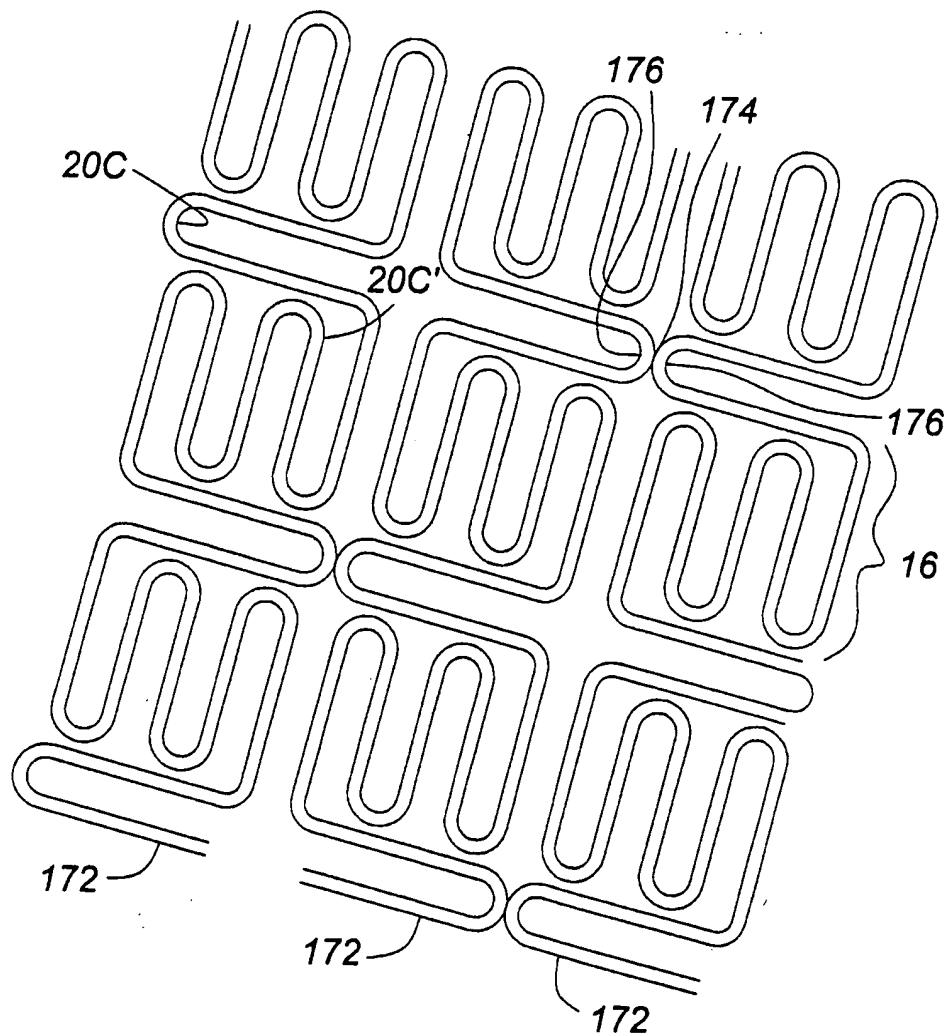


FIG. 18

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**FIG. 19**

INTERNATIONAL SEARCH REPORT

Int'l. Application No.
PCT/CA 00/00035

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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P, X	EP 0 910 998 A (CORDIS CORP) 28 April 1999 (1999-04-28) claims; figures	1, 4, 5, 7, 11, 14, 20, 21, 23-25, 27, 35, 38
X	US 5 843 175 A (FRANTZEN JOHN J) 1 December 1998 (1998-12-01) claims; figures	1-5, 8, 10-18, 22
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

8 May 2000

Date of mailing of the international search report

19/05/2000

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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